

**SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK**

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

v.

Dept. of Health & Mental Hygiene of the City of New
York,

Defendant-Respondent.

**VERIFIED ARTICLE 78 AND
DECLARATORY JUDGMENT
PETITION**

VERIFIED ARTICLE 78 AND DECLARATORY JUDGMENT PETITION

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Plaintiffs-Petitioners, by and through their undersigned counsel, respectfully allege the following based on their own knowledge as to themselves, and on information and belief as to all other matters:

PRELIMINARY STATEMENT

1. In the spring of 2019, New York City experienced a rise in measles cases. Measles is a childhood infection caused by a virus that, before the 1960s, nearly all children contracted before the age of 15. Most measles cases are benign and are not reported. (**Ex. A**).¹ The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in the United States. (**Exs. A and B**). In 1962, a year before the first measles vaccine, when there were approximately 4 million cases of measles each year, the Centers for Disease Control (“**CDC**”) reported a total of 408 deaths from measles in the entire United States.

2. Between September 2018 and August 2019, 649 cases of measles were confirmed in New York City. Since 2000, the annual number of reported measles cases for all of the United States ranged from 37 people in 2004 to 667 people in 2014. While 600 cases in New York City alone was, relatively speaking, an unexpected increase in cases, it was a very small number in a city of over 8,000,000. While over 1,200 cases of measles were reported in the tri-state area and likely far more unreported cases, there were no deaths. This is the expected result since, for the majority of people, measles is a relatively benign childhood infection.

3. Despite the small outbreak, the New York City Department of Health (“**DOH**”) overreacted to the 2019 increase in measles cases. On Friday, April 9, 2019, Oxiris Barbot, the then New York City Commissioner of Health and Mental Hygiene (the “**Commissioner**”) issued

¹ All Exhibits referenced in this Petition, and in the jointly filed Affirmation of Elizabeth A. Brehm, are exhibits admitted without objection at the OATH hearing, described further herein, or are otherwise part of the administrative record.

an Order mandating that people receive the M-M-R-II, also known as the measles, mumps, rubella vaccine (“**MMR**”) manufactured and sold by Merck & Co., within forty-eight hours (the “**Commissioner’s Order**”). (Ex. C). The Commissioner’s Order though, was limited to only selected people in certain zip codes and was not evenly applied across the city. Specifically, the Order required MMR vaccination only of certain people: any person “older than six months of age who live[d], work[ed], or reside[d] within the 11205, 11206, 11211 and/or 11249 zip codes.” *Id.*

4. By its terms, the Commissioner’s Order expired on April 17, 2019. (Ex. D at 56:23-57:7; 63:23-64:2). On that day, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “**Board**”) created a resolution which, like the Commissioner’s Order, required administration of the MMR, but differed from the Commissioner’s Order in myriad ways. These differences included: how it defined what the “nuisance” was that it was targeting, what categories of individuals it applied to, the age ranges to which it applied, the penalties for failure to vaccinate, and other material differences as detailed below (the “**Resolution**”). (Ex. E).

5. Between April 23, 2019, and June 14, 2019, the New York City Department of Health and Mental Hygiene (“**DOH**”) issued a Summons to each of the Plaintiffs-Petitioners, asserting that each had failed to have one of their minor children injected with the MMR (the “**Summonses**”). The Summonses clearly and prominently alleged that this failure to vaccinate violated the Commissioner’s Order, not the Resolution. However, the DOH issued each of the Summonses after the Commissioner’s Order expired, making each Summons facially invalid. (Ex. F).

6. Plaintiffs-Petitioners had a reasonable and well-founded belief that they should not administer the MMR to their children (the “**children**”) for many reasons, including, *inter alia*:

a. The clinical trials conducted on the MMR were severely lacking in adequate

- safety studies because (i) the studies did not test the product against a placebo, (ii) the studies did not test the product on a large enough group of children of an appropriate age range, (iii) the studies did not review safety for an adequate time period, and, (iv) during the minimal safety review period, the safety studies showed concerning adverse events;
- b. Medical studies have shown that depriving children of having naturally occurring measles increases their risks of other adverse health outcomes; and
 - c. The medical community has documented high rates of hospitalization and emergency room visits subsequent to MMR administration.

Based on these concerns, Plaintiffs-Petitioners made the decision that the risks of the product outweigh the benefit, and that administering MMR to their children is not medically appropriate.

7. Given the facial defects in the Summonses and their well-founded concerns about the MMR product, Plaintiffs-Petitioners fought the Summonses in OATH where, despite making compelling arguments and presenting unrebutted evidence supporting the above issues, the hearing officer upheld the Summonses, and the OATH Appeals Unit affirmed those decisions on April 24, 2020. (Ex. G).

8. The hearing record, however, reflects that the Summonses should have been dismissed and that the Hearing Officer deprived Plaintiffs-Petitioners of full and fair hearings, made errors of law, and issued arbitrary and capricious decisions. (*Infra* § First Cause of Action.)

9. The OATH Appeals Unit should also have dismissed the Summonses in the interest of justice pursuant to NYCC § 1049(5)(a) because the undisputed evidence at the hearing demonstrated that the risk of administering the MMR to these children outweighed the benefits

and therefore it was not medically appropriate to inject them with this product. (*Infra* § Second Cause of Action).

10. By requiring the injection of a product whose risks outweigh the benefits for these children, Respondent's Order and Resolution also violated Plaintiffs-Petitioners' rights under the United States Constitution and New York State Constitution, including the right to bodily integrity, informed consent, parental choice, privacy, and other substantive due process and unenumerated rights. (*Infra* § Third Cause of Action.)

11. Plaintiffs-Petitioners thus bring this hybrid petition pursuant to CPLR §§ 7801-7806 to set aside and vacate the Summonses.

PARTIES

12. Plaintiffs-Petitioners Ascher Berkowitz, Chava Biederman, Beila Englander, Israel Fishman, Judith Fried, Malka Friedman, Chanie Fulop, Rachel Guttman, Simon Josef, Baila Klein, and Malky Roth-Tabak (collectively "**Plaintiffs-Petitioners**") reside in Brooklyn, NY and were issued a Summons for their respective child: Z.B., 4 years old; B.B., 2 years old; Z.E., 1 year old; A.F., 3 years old; H.F., 7 months old; Y.F., 5 years old; D.F., 11 months old; E.G., 2 years old; P.J., 4 years old; Z.K., 11 months old; C.R., 1 year old. Many of the Plaintiffs-Petitioners have more than one child and many of the Plaintiffs-Petitioners vaccinate their other children.

13. Defendant-Respondent the New York City Department of Health and Mental Hygiene ("**Department of Health**" or "**DOH**" or "**Respondent**") is an administrative agency in the executive branch of the New York City.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction to decide this Petition pursuant to CPLR § 7803 because the decisions made by the OATH Appeals Unit are final determinations made in

violation of lawful procedure, affected by an error of law, and are arbitrary and capricious. This Court also has jurisdiction to render a declaratory judgment pursuant to CPLR § 3001.

15. This Court has personal jurisdiction over Respondent pursuant to CPLR § 302(a)(1) and venue lies in New York County pursuant to CPLR § 506(b) and §7804(b) because it is where material events giving rise to the petition took place; specifically, the OATH appellate decisions that are being challenged here were rendered in New York County.

**FIRST CAUSE OF ACTION: THERE WERE ERRORS OF LAW IN RESPONDENT’S
FINAL DETERMINATIONS**
(Relief Under Article 78 of the CPLR)

16. Plaintiffs-Petitioners repeat and reallege the preceding paragraphs as though fully set forth herein.

17. It is black letter law that a summons must identify the exact law, regulation, or order that the charging officer claims the recipient violated. RCNY § 6-08(c)(2) and (c)(3). It is equally well established that such a law, regulation, or order must be in effect at the time of the alleged violation. Here, the Summonses failed on both accounts.

18. The DOH issued the Summonses between April 23, 2019 and June 14, 2019. The charging language of the Summonses provides that Plaintiffs-Petitioners were in violation of the Commissioner’s Order. However, the Commissioner’s Order by its terms expired on April 17, 2019. Given this defect, the OATH Appeals Unit reasoned that the Summonses were actually issued under the Board’s Resolution, but that is not what the Summonses say, and the Resolution is significantly different from the Order in a number of ways. Thus, the Summons either cite an order that had expired, or they cited to the wrong order. Either way, the Summonses are facially deficient and should have been dismissed.

19. The narrative portions of the Summonses specifically reference both the Commissioner's April 9, 2019 Order, which they define as the "Order", and the Board's April 17, 2019 resolution, defining it as the "Resolution." (Ex. F).² Nevertheless, the charging language of the Summonses identifies the violation as being a violation of the *Order*, providing in full that: "Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*." *Id.* (emphasis added.) As such, the summonses are clear that they allege a violation of the Order, and not of the Resolution. (Ex. F).

20. During the hearings on the Summonses, the DOH conceded that the Commissioner's Order expired on April 17, 2019. (Ex. D at 56:34-57:7; 63:23-64:2). The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" Health Code of the City of New York, 24 RCNY § 3.01(d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

² The full text of the "Violation Description" provides as follows and clearly defines both the Resolution and the Commissioner's Order, recognizing them as separate, but then choose to only state that the Plaintiffs-Petitioners are in violation of the Order: "In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, [initials], who is at least six months old, lives at: [address] which is located in one of the affected zip codes listed in the Order. On [date], a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child [initials] has no record of measles immunization. Respondent has failed to vaccinate child [initials] or otherwise submit proof of immunity *in violation of the Order*." (Ex. F) (emphasis added).

21. The Summonses each listed a “Date and Time of Occurrence” after April 17, 2019.³ (Ex. F). Therefore, the Order had expired by the time the Summonses were issued, and it was an error of law for the Hearing Officer and Appeals Unit to affirm the Summonses because the Commissioner’s Order had expired by the date of the occurrence listed on the Summonses. (Exs. C and F). On this basis, the Summonses must be dismissed.

22. During the hearing, the DOH argued that despite the fact that the Order expired before the Summonses were issued, the Resolution continued the Commissioner’s Order, and thus the Commissioner’s Order was still valid on the date of occurrence on the Summons. This argument is plainly incorrect. The New York City Health Code provides that “the Board may *continue* or *rescind*” the Order. Health Code of the City of New York, 24 RCNY § 3.01(d) (emphasis added). On its face, that section allows the Board only to continue the order “as is” or to rescind the order and issue a new order. Nothing in that section states that the Board may *amend* the emergency order.

23. In this instance, the Board did not continue the Commissioner’s Order. Even though the Resolution acknowledges the Commissioner’s Order in the preamble, nothing in the Resolution states it is continuing the Commissioner’s Order. Instead, the Board allowed the Commissioner’s Order to expire and subsequently issued the Resolution, which was a new order, with materially different terms. Even a cursory examination of a few of these terms establishes that the Commissioner’s Order and the Resolution, although they address the same topic, are two different directives, and as such, one is not a continuation of the other.

³ Plaintiffs-Petitioners’ Summonses listed the following “Date and Time of Occurrence:” Berkowitz Summons: June 4, 2019; Biederman Summons: April 29, 2019; Englander Summons: May 1, 2019; Fishman Summons: June 12, 2019; Fried Summons: May 10, 2019; Friedman Summons: June 4, 2019; Fulop Summons: May 22, 2019; Guttman Summons: June 13, 2019; Josef Summons: June 4, 2019; Klein Summons: May 1, 2019; Roth-Tabak Summons: April 21, 2019. (Ex. F).

24. *First*, the Resolution redefines what constitutes a nuisance. The Order defines the nuisance as the presence of a person who was not vaccinated with MMR.⁴ The Resolution defines the nuisance as the measles outbreak.⁵

25. *Second*, the Resolution materially changed who must receive an MMR vaccination, as well as the grounds and method for being excluded from this requirement:

- a. The Commissioner's Order does not include children who attend school, preschool, or child care in the affected zip codes (it only includes "any child older than six months of age who *live[]*, *work[]* or *reside[]* within the" affected zip codes), whereas the Resolution explicitly includes children who "attend[] school, preschool or child care within the affected zip codes." (**Ex. C**).
- b. The Commissioner's Order applies to children "older than six months," but the Resolution applies to children "six months of age and older." (**Exs. C and E**). Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order includes people who "live, work, or reside[]" in the affected zip codes, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. (**Exs. C and E**). The Board's decision to not include people who "reside" in the zip code is important. Merriam-Webster's

⁴ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" (**Ex. C**).

⁵ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" (**Ex. E**).

dictionary defines “reside” to mean: “to dwell permanently or continuously: occupy a place as one’s legal domicile.”⁶ Conversely, that same dictionary defines “live” as: “to pass through or spend the duration of[.]”⁷ Thus, the Commissioner’s Order, by use of the term “reside,” includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (*e.g.*, people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution is limited to the people who are physically present in the area.

- d. The Commissioner’s Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of the DOH.⁸

26. *Third*, the penalties for the Commissioner’s Order are different than the penalties for the Resolution. The Commissioner’s Order includes a “warning” that “[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.” (Ex. C). The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code, 24 RCNY § 3.11(a), and subjecting violators to fines for each family member and for each day a person violates the

⁶ Merriam-Webster’s Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>.

⁷ Merriam-Webster’s Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>.

⁸ The terminology may seem similar between the Commissioner’s Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

Resolution. This “enhanced” civil penalty did not appear in the Commissioner’s Order but is included in the “resolved” language of the Resolution.⁹

27. In sum, the Resolution materially changed the Commissioner’s Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner’s Order. The Resolution plainly created a new and distinct order, which means that per the requirements of the Health Code of the City of New York, 24 RCNY § 3.01(d), the Commissioner’s Order expired on April 17, 2019.¹⁰ Thus, the Board’s assertion that the Plaintiffs-Petitioners violated the Order was *per se* unlawful.

28. Despite the clear differences between the Order and the Resolution, the Hearing Officer still held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” (Ex. G). As shown, this finding is not supported by the facts and law. The Hearing Officer could not even quote any language from the Resolution stating it continues the Order, because such language does not exist; that is why he resorted to stating that the “Resolution continued the Commissioner’s exercise of emergency authority.” As noted, that

⁹ “RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.” (Ex. E).

¹⁰ The Summons issued to one of the Plaintiffs-Petitioners was not properly served. The Summons issued to Plaintiff-Petitioner Chava Biederman (“**Ms. Biederman**”) should be dismissed because Ms. Biederman does not reside at the address listed on the Summons as the “Place of Occurrence” and Ms. Biederman was not present at the “Place of Occurrence” when the alleged violation took place on April 29, 2019. Ms. Biederman presented sufficient and reliable evidence at the hearing that she did not live or reside at the “Place of Occurrence” as listed on the Summons and was not present at that location on the time and date of occurrence. (Ex. H). Therefore, it was an error of law for the Hearing Officer and Appeals Unit to sustain the Summons because no violation existed as alleged, and thus the Summons issued to Ms. Biederman must be dismissed.

is not what the law provides. The Order as it was written must either be continued or rescinded; the Board cannot choose to continue the Order in concept while changing most of its terms.

29. This case provides a ready example of why the Board was not allowed to amend an existing order, because otherwise a summons recipient could be told he or she violated one order, choose to mount a defense to that order, but only later learn that they actually are being charged with violating and being punished under a materially different order. This presents a problem here because the Order and the Resolution provided conflicting provisions as to, *inter alia*, the individuals who were required to receive MMR, the penalties for not receiving the MMR, and the method and grounds for obtaining a medical exemption. As a matter of both fact and common sense, they both cannot exist in the same time and space. This bait-and-switch version of justice, where a litigant does not have proper notice of what they are accused of, flies in the face of the basic presumptions of due process.

30. Tellingly, the OATH Appellate Unit did not affirm the OATH Hearing Officer's flawed conclusion that the Resolution continued the Order. The OATH Appellate Unit apparently found it to be without merit. Instead, the OATH Appellate Unit decided that since the children presumably did not have the MMR during the period the Order *was* in effect (giving no consideration to the period after the Order expired), then it would uphold the Summonses by effectively rewriting them; instead of the "Date and Time of Occurrence" for the violation listed on the Summonses, the OATH Appellate Unit decided it would simply find the Plaintiffs-Petitioners in violation for a completely different time period: the 48 hours specified in the Order.

31. The problem with the OATH Appellate Unit's decision is that it apparently changed the Summonses that were being adjudicated *ex post facto* - after the hearing record was closed - which it cannot do.

32. It is elementary and critical to due process that a respondent only be judged on and punished for what the summons charges. Here, that charge was for violation of the Order on a date after it expired, not for a violation that occurred on some other date first raised in a decision by an appellate body. That is the antithesis of due process and the orderly manner in which justice is supposed to proceed.

**SECOND CAUSE OF ACTION: NYCC § 1049(5)(a) CALLS FOR THE DISMISSAL OF
THE SUMMONSES IN THE INTEREST OF JUSTICE**
(Relief Under Article 78 of the CPLR)

33. Plaintiffs-Petitioners repeat and reallege the preceding paragraphs as though fully set forth herein.

34. Section 1049(5)(a) of the NYCC provides:

An administrative law judge or hearing officer may dismiss a notice of violation in the interest of justice when, even though there may be no basis for dismissal as a matter of law, such dismissal is appropriate as a matter of discretion due to the existence of one or more compelling factors, considerations, or circumstances clearly demonstrating that finding the respondent in violation of the provision at issue would constitute or result in injustice.

35. The Summonses should have been dismissed pursuant to NYCC § 1049(5)(a) because the undisputed evidence entered at the hearing reflected that the risk of injecting the MMR into these children outweighs any benefits. Plaintiffs-Petitioners presented significant evidence establishing this as a fact, and the DOH never once objected to or refuted any of that evidence. Therefore, for purposes of this matter, it is an established fact that MMR presents greater dangers than the benefits it brings. If the interest of justice does not tip in favor of dismissal when the evidence incontrovertibly reflects the injustice of a risk of increased harm to a child, then the safeguard afforded by NYCC § 1049(5)(a) is meaningless.

36. The first vaccine for measles was licensed in the United States in 1963. (**Ex. A**). According to the CDC, the mortality rate from measles declined by over 98% between 1900 and 1962. (**Exs. A and B**). In 1962, the CDC reported a total of 408 deaths from measles in the United States. (**Ex. D at 207:18-21**). The CDC reported a similar total number of measles deaths in the United States for a number of years prior to 1962. (**Ex. B**). What this means is that prior to 1962, at a time when virtually every American had the measles, the CDC's data makes clear that the annual death rate from measles was 1 in 500,000 Americans.

37. There would likely be even fewer deaths from measles today, since medical care has made significant advances since 1962. But even assuming the same medical care today as in 1962, the unrebutted science admitted at the hearing makes clear that the measles vaccine MMR causes more deaths every year than the 400 individuals lives it theoretically saves annually.

38. Indeed, eliminating measles has demonstrably and measurably increased certain cancer rates as well as the risk of heart disease.¹¹ The International Agency for Research on Cancer has confirmed that those who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma and a 233% increased rate of Hodgkin Lymphoma. (**Exs. L-P**). These two cancers killed 20,960 Americans in 2018. *Id.* Plaintiffs-Petitioners presented copious evidence supporting this conclusion at the hearing without objection and the DOH never attempted to rebut that evidence.

39. Likewise, researchers at the Department of Health Care and Epidemiology at the University of British Columbia and the Department of Biology at the University of Victoria have confirmed that those who never had measles had a 50% increased rate of ovarian cancer, which

¹¹ Additionally, **Exs. I-K** reflect that children who have had measles have far less allergies and atopic diseases, such as asthma, and adults who had measles have a reduced risk of Parkinson's Disease. It is not medically appropriate or just to increase an individual's risk of allergies, atopic diseases, or Parkinson's Disease.

killed 14,070 Americans in 2018. (Exs. Q-R). Again, this was accepted at the hearing without objection and remained unrebutted.

40. Even more troubling was the fact that the nation of Japan concluded, after tracking over 100,000 of its citizens for more than 22 years, that having measles and mumps was “associated with lower risks of mortality from heart disease,” which killed 610,000 Americans in 2018. (Exs. S-T). Once again, Plaintiffs-Petitioners presented the evidence establishing this fact on the record without objection, and Defendant-Respondent never once presented anything to rebut that evidence.

41. Until the introduction of the vaccine, measles was considered a mild childhood infection, like the chickenpox used to be. The ecological relationship humans developed with measles over millennia did not eliminate measles or ensure that only those that survived were those that were immune to the disease because it conferred benefits for survival that exceeded its negative effects.

42. Hence, the unrebutted evidence shows that eliminating measles has likely caused far more deaths annually in the United States from cancer and heart disease than the potentially few hundred lives saved from the elimination of measles.

43. The foregoing facts presented at the hearing demand that the Summonses be dismissed because the accepted and unrebutted evidence demonstrates an increased, not decreased, risk of mortality from complying with the Order. The DOH was given every opportunity to rebut this evidence yet it chose not to do so.¹²

¹² The DOH and Dr. Rosen objected to none of the admitted evidence at the hearing nor did they rebut any evidence. They had myriad opportunities to oppose, contest, or dispute this evidence being entered into the record and they did not:

MR. LEUNG: Well, let me just say something. These are both hearings and attorney statements. When you come in, it is testimony to the extent that your introducing these documents. And you can testify in place of your client.

44. The DOH brought Dr. Jennifer Rosen to the OATH hearings to testify as the agency's physician.¹³ Dr. Rosen's resume shows that she had significant training and experience in childhood immunization, including through her work at the Howard Hughes Medical Institute, and the CDC. Since 2009, Dr. Rosen has been at the New York City Department of Health and is currently the Director of Epidemiology and Surveillance for the Bureau of Immunizations. There, she oversees surveillance and outbreak investigations for vaccines and preventable diseases, including measles.

MR. SIRI: Okay.

MR. LEUNG: You can testify in place of the client's doctor. You can testify -- triple hearsay is permitted. Whatever you need to say, I'm taking into consideration. Everything is testimony

...

MR. LEUNG: The documents that have been admitted so far all the way up to Respondent's 39. Department of Health, any objections? Any objections to those being admitted into evidence?

MR. MERRILL: No objections.

MR. LEUNG: Okay. They're admitted into evidence.

...

MR. LEUNG: But you spoke at length and I want to give the Department of Health, Mr. Merrill, an opportunity to address all the issues that they have. Is there anything else that you want to add?

MR. MERRILL: No.

...

MR. LEUNG: ... I have given a chance to the Department of Health to review that. Any objection going up to R-45?

MR. MERRILL: No, your Honor.

MR. LEUNG: Hearing no objections, these are admitted into evidence. And hearing nothing further from either parties; is that correct.

MR. MERRILL: That's right.

(Ex. D at 211:7-20; 226:24-227:11; 239:2-9; 242:9-243:7).

¹³ Because of the proven potential for adverse events following this product, and because the Summons calls for a fine to Plaintiffs-Petitioners "unless they demonstrate...that immunization is not medically appropriate," counsel for Plaintiffs-Petitioners proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. "A respondent may request the [issuing officer's] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful." *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). The Defendant-Respondent objected and argued the issuing officer was not necessary since Dr. Rosen was available and could answer any questions. **(Ex. D at 9:1-9:20)**. Based on same, the Hearing Officer declined Plaintiffs-Petitioners' application to cross-examine the issuing officer, holding that Dr. Rosen was available and could answer any questions regarding these disputed facts. **(Ex. D at 14:4-22)**.

45. Not only did the DOH and Dr. Rosen not object to, nor provide any evidence to contradict, what Plaintiffs-Petitioners presented during the first hearing date, August 28, 2019, but they also did not do so when they had a second bite at the apple during the follow-up hearing date, September 25, 2019.

46. The fact that this evidence went unrebutted means that, based on the record presented during the hearing, Plaintiffs-Petitioners established that the Order requires Plaintiffs-Petitioners to inject a product into their children that has been medically established to increase mortality, and will expose their children to far greater risks of a number of conditions later in their lives.

47. In addition, the following facts regarding the harms from this product also remained unrebutted.¹⁴

48. The Order requires injection of M-M-R-II,¹⁵ a product which was licensed by the FDA based on clinical trials which had a total of 834 children, had no placebo control, and only reviewed safety for 42 days after injection. (**Ex. BB**). Putting aside the lack of placebo control, even if the clinical trials were properly controlled, they did not have enough individuals to assess safety; nor did they review safety for long enough. They also included children of limited ages: most were ages 11 months to 8 years old, while the Order is seeking to have M-M-R-II used by children aged 6 months.¹⁶

¹⁴ Physicians have separately detailed the benefits and risks of the MMR in **Ex. A**.

¹⁵ **Ex. V** lists the excipient and media contained in the MMR, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin. **Exs. W-Y** are product descriptions and history of the use of these ingredients and excipients. **Ex. Z-AA** explain the existence of aborted fetal cells' use in vaccines and the potential adverse effects of such use.

¹⁶ It was, therefore, arbitrary and capricious for the Hearing Officer to sustain the Summonses mandating the MMR for a child less than twelve months old. Plaintiff-Petitioner Judith Fried's ("**Ms. Fried**") child was 9 months old at the time of the alleged violation. (**Ex. CC**). However, the Food and Drug Administration ("**FDA**") has not licensed MMR for children less than twelve months old. Ms. Fried presented undisputed evidence at the hearing that the MMR is not licensed for this age group and that the "safety and effectiveness of mumps and rubella vaccine in infants

49. Despite the fact that approximately a third of the children in the clinical trials developed gastrointestinal issues and respiratory issues within 42 days of receiving the MMR, due to their underpowered size and lack of follow-up, they were able to avoid this being a roadblock to licensure. Despite MMR being licensed, the clinical trials clearly did not, as they could not, confirm that the product was safe, and certainly not for any period longer than 42 days, nor for even the 42 days they did review safety. For example, the below table is the safety data from one of the largest clinical trials, which had a total of just 102 children injected with MMR, relied upon to license MMR:

less than 12 months of age have not been established.” **(Ex. DD)**. Therefore, the Summons and the Hearing Officer’s order are both saying that Ms. Fried’s child must receive the MMR even though the FDA has not determined that it is safe or effective for the child. This is patently arbitrary and capricious because there is no reasonable basis for the Hearing Officer to uphold a violation for failure to inject a child with MMR where the vaccine is not licensed for use in the child. Finally, the Hearing Officer failed to address this argument in his written decision, further making the decision arbitrary and capricious.

Table 0

Clinical Complaints Reported Among Children Who Received a 0.5 Ml Dose of Combined Live Polio-Hepatitis B (DA 275) Virus Vaccine, Lot No. 621/C-0163 (Study 444)

Clinical Complaint	Total Vaccines (102 Children)					No. with Complaint	Initially Seronegative for Measles, Mumps and Rubella (48 Children)					No. with Complaint
	Days Post-Vaccination						Days Post-Vaccination					
	0-4	5-11	12-18	19-28	29-42		0-4	5-11	12-18	19-28	29-42	
Soreness at Injection Site	4 (4.2%)			1 (1.0)		5	2 (1.0)					2
Lymphadenopathy	2 (2.1)	3 (3.1)		2 (2.1)	2 (2.1)	6	1 (1.5)	1 (1.5)		5 (3.0)	2 (3.0)	3
Rupee-like Rash	1 (1.0)	6 (9.9)	8 (6.2)	1 (1.0)	1 (1.0)	13	1 (2.5)	2 (10.4)	5 (7.5)	1 (1.5)		9
Arthralgia			1 (1.0)	1 (1.0)		2			1 (1.5)	1 (1.5)		2
Myalgia		1 (1.0)				1		1 (4.5)				1
Ferretability	2 (3.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	6	2 (2.9)	2 (2.9)	1 (1.5)	1 (1.5)		3
Headache	2 (2.1)	2 (2.1)				2	2 (3.0)	2 (3.0)				2
Upper Respiratory Illness	18 (31.6)	37 (39.5)	24 (25.8)	35 (36.5)	35 (35.3)	64	18 (41.0)	20 (40.3)	20 (29.8)	28 (27.3)	29 (29.8)	48
Stiff	1 (1.0)	7 (7.3)	2 (2.1)	5 (5.2)	4 (4.2)	14	1 (1.5)	4 (6.0)	2 (3.0)	3 (4.5)	2 (3.0)	9
Ophthalmopathy	2 (3.1)	3 (3.1)	2 (2.1)	4 (4.2)	2 (2.1)	6	2 (3.0)	3 (4.5)	2 (3.0)	4 (4.0)	2 (3.0)	6
Gastrointestinal Illness	18 (31.6)	20 (21.0)	8 (9.4)	17 (17.7)	18 (15.6)	43	18 (20.9)	18 (29.4)	8 (12.4)	14 (20.9)	11 (16.4)	35
Anorexia	11 (12.5)	17 (19.8)	8 (6.2)	10 (10.4)	13 (12.5)	29	10 (14.9)	12 (17.9)	8 (9.0)	9 (16.4)	9 (16.4)	20
Fatigue				3 (1.0)		3				1 (1.5)		1
Back-Chafing, Diaper, Heat, Itches	4 (4.2)	4 (4.2)	1 (1.0)	4 (4.2)	5 (4.7)	12	3 (4.5)	6 (6.0)	1 (1.5)	3 (4.5)	5 (4.5)	9
Allergy, Anemia	1 (1.0)	2 (2.1)	3 (2.1)	2 (2.1)	3 (3.1)	6		1 (1.5)	2 (3.0)	1 (1.5)		3
Fever	1 (1.0)	1 (1.0)		2 (2.1)	1 (1.0)	4		1 (1.5)		1 (1.5)		2
Autocoids	1 (1.0)					1	1 (1.5)					1
Tearing	3 (3.0)			1 (1.0)	3 (3.0)	6	4 (4.5)			1 (1.5)	3 (4.4)	6
Persons with Complaints:	50 (32.1)	50 (51.1)	31 (31.4)	43 (44.8)	44 (45.8)	78	38 (56.7)	38 (56.7)	28 (41.3)	32 (47.8)	30 (44.8)	56
Persons with No Complaints:	44 (67.9)	46 (47.9)	69 (65.6)	57 (55.2)	57 (56.2)	18	27 (43.3)	27 (43.3)	38 (56.7)	35 (52.2)	31 (45.2)	9
Negative Physical Surveillance	6	6	6	6	6	6	1	1	1	1	1	3

5/6/27

The table above shows that of 102 children injected with MMR, 64 of them, or nearly 63%, experienced gastrointestional illness and that 43, or 42%, of the children experienced upper respiratory illness within the first 42 days following administration. All of the foregoing was accepted without objection during the hearing.

50. The following un rebutted facts confirm that there are also numerous safety issues with this product that have arisen after licensure.¹⁷

¹⁷ Exs. EE-II are reports from the IOM which looked at the components of the MMR. The IOM looked at the 22 most commonly claimed serious adverse reactions after the MMR and reported that, for 18 of the 22, they were not able to determine whether or not the MMR components caused them due to a lack of science. The IOM stated: "The lack of adequate data regarding many of the adverse events under study was a major concern to the committee." The IOM further explained that "most individuals who experience an adverse reaction to vaccines have a preexisting

51. Federal law expressly provides that the package insert for a vaccine like M-M-R-II should include “*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.” (Ex. D at 217:19-218:16). The package insert for M-M-R-II lists approximately 60 such adverse reactions that Merck has identified, many of which are serious and debilitating. (Ex. DD). For instance, during the hearing, Plaintiffs-Petitioners introduced into evidence two examples of Merck recently adding adverse reactions to its M-M-R-II package insert. The first was the addition of “transverse myelitis” (neurological dysfunction of the spinal cord) which was added to the list in 2014; and “Henoch-Schonlein purpua” (a vascular disease that primarily affects small blood vessels) and “acute hemorrhagic edema of infancy” (a type of leukocytoclastic vasculitis which manifests with fever, large palpable purpuric skin lesions, and edema) which were added to the list in 2017. (Ex. JJ).

52. The CDC even discloses that MMR can cause deafness, long term seizure, coma, and brain damage.¹⁸ (Ex. KK). An example of such an injury was presented at the hearing involving a \$100 million award to the victim of an MMR injury was presented at the hearing. (Ex. LL). The CDC and FDA also jointly operate the Vaccine Adverse Events Reporting System (“VAERS”) which, as an example provided at the OATH hearing, reflected 1,256 hospitalizations and/or emergency room visits in one year following MMR vaccination. A report from Harvard researchers, under a federal grant, stated that VAERS reflects fewer than 1% of vaccine adverse events.

53. This high rate of hospitalization and emergency room visits from MMR is likewise confirmed in a study conducted by Canadian health authorities of 271,495 children after their 12-

susceptibility” yet no studies have been conducted to identify those who are susceptible.

¹⁸ And like most vaccines, the MMR has never been evaluated for its potential to cause cancer, to mutate genes, or to cause infertility. (Ex. DD).

month MMR. The Canadian health authorities set out to confirm the safety of MMR, but what they found instead was that “[t]here was a significantly elevated risk of primary emergency room visits approximately one to two weeks following 12- and 18-month vaccination.” (Ex. MM). This amounted to an additional “one event for every 158 vaccinated” children receiving MMR. Extrapolating these figures to the United States, it means that 63,291 additional children would be going to the hospital each year from MMR after their MMR vaccine (based on the CDC’s representation that, each year in the United States, nearly 10 million doses of MMR are distributed).

54. Dr. Rosen also did not refute or even dispute any of the evidence regarding post-marketing safety issues with MMR at the hearing; in fact, all this evidence was accepted without objection.¹⁹

55. After the current MMR’s licensure in 1978, its use in children steadily increased and lawsuits from injuries from this product also began to snowball. Indeed, by the mid-1980s – when the only two commonly injected childhood vaccines were MMR and DTP – pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products. (Ex. D at 184:24-186:18, Ex. NN). As the United States Supreme Court explained in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011): “by the mid-1980’s ... the remaining [vaccine] manufacturer estimated that its potential tort liability exceeded its annual sales by a factor of 200.”

56. Instead of letting the usual market forces drive pharmaceutical companies to

¹⁹ See paragraphs 42-45, supra. Additionally, Dr. Rosen was not able to rebut that the risks outweigh the benefits for these children even though most of the hearing time was devoted to the Hearing Officer improperly interjecting to protect Dr. Rosen from difficult questions and/or Dr. Rosen refusing to provide responsive answers to questions. (Ex. D at 153:14-18 and generally).

develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), in 1986, which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccine products.²⁰

57. While the manufacturers of the MMR and other childhood vaccines have paid billions of dollars for misconduct and injuries related to their drug products, these same companies cannot be held accountable for misconduct and injuries resulting from their vaccine products, including the MMR. (**Ex. OO**). Dr. Jennifer Rosen, the DOH’s physician who testified at the OATH hearing and who the DOH said could answer any questions Plaintiffs-Petitioners had, was not aware of this fact.²¹

58. When provided an opportunity to rebut any of the foregoing evidence, the DOH declined to proffer any evidence in rebuttal, accepted the foregoing evidence without objection, and despite prodding from the Hearing Officer, neither the DOH nor Dr. Rosen had any additional argument, statement or evidence to present to rebut any of the foregoing.

59. Indeed, when provided multiple opportunities to object to any of this evidence, the DOH declined to do so. The Hearing Officer repeatedly asked for objections: “Department of Health, any objections? Any objections to those being admitted into evidence?” DOH’s attorney repeatedly responded: “No objections.” (**Ex. D at 227:6-11**). After additional evidence was

²⁰ 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

²¹ “Q. So you are not aware that the manufacturer of the MMR vaccine, Merck, cannot be sued for injuries caused by their MMR vaccine? A. I am not familiar with the process for manufacturing companies. Q. Are you aware -- but are you aware that -- if you could answer yes or no on that one. A. No, I am not aware. Q. You are not aware of that. So you are not aware that Merck can[not] be sued for injuries caused by the MMR vaccine? A. No.” (**Ex. D at 101:24-102:12**).

entered, the Hearing Officer again gave the DOH the chance to object: “Any objection going up to R-45?” DOH’s attorney responded, “No, your Honor.” (**Ex. D at 242:9-17**).

60. Thus, the undisputed evidence reflects that the mandated MMR was not medically appropriate for the children, as the risks of injecting this product into the children outweigh the benefits.²²

61. For these reasons, the record here reflects that the DOH is seeking to mandate injection of a liability-free product that has not been proven to be safe and whose risks outweigh any believed benefit. The potential adverse events that can follow the administration of the MMR and the lack of support for their benefit overshadow any rash overreaction by the DOH. Imposing a fine on these families for choosing what the evidence reflects is best for their children’s overall health is unjust. The Court should, therefore, find that Respondent’s final determinations are affected by an error of law and are arbitrary and capricious.²³

**THIRD CAUSE OF ACTION: REQUIRING INJECTION OF M-M-R-II VIOLATES
THE UNITED STATES AND THE NEW YORK CONSTITUTIONS**
(Declaratory Relief Under Article 30 of the CPLR)

62. Plaintiffs-Petitioners repeat and reallege the preceding paragraphs as though fully set forth herein.

63. The Commissioner’s Order and Resolution violate the New York and United States Constitutions.

²² Indeed, the one study that looked at health outcomes of children who were vaccinated versus children who were not vaccinated found that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders than the unvaccinated. *See Ex. PP*. It is not medically appropriate or just to force an individual to trade avoidance of a limited infection for a chronic health condition.

²³ Plaintiffs-Petitioners admitted additional, un rebutted evidence at the OATH hearings. Those exhibits are appended at **Exs. QQ-XX**.

64. Because the un rebutted record reflects that the risk of injecting a medical product outweigh its benefits, including a significant increased risk of mortality from being injected with the product, the United States Constitution and New York State Constitution extend their shield of protection to prevent the government from requiring such an injection.

65. Specifically, requiring injection of M-M-R-II into the bodies of the Plaintiffs-Petitioners' children violates both federal and state constitutional rights to substantive due process, bodily integrity, informed consent, parental choice, privacy, unlawful search and seizure, other unenumerated rights, and the First Amendment protection of freedom of religion.

A. Substantive Due Process and Fundamental Rights to Life and Liberty

66. The United States and the New York State Constitutions guarantee substantive due process rights to life and liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

67. The absence of any effective exemption to the Order or the Resolution denies Plaintiffs-Petitioners and their children of these rights to life and liberty.

68. It is a deprivation of the right to liberty, of both Plaintiffs-Petitioners and their children, to coerce a parent, under threat of a violation and civil punishment, to inject their child with a product when their informed decision based on review of the existing literature regarding this product, their religious beliefs, and their intimate knowledge of their child, including the child's medical and familial history, is to not inject their child with this product.

69. Threatening a violation and civil punishment upon the refusal to inject a product that a parent has not consented to and, where the un rebutted science reflects it will increase mortality, infringes upon Plaintiffs-Petitioners' and their children's substantive right to life.

B. Fourth Amendment

70. The Fourth Amendment to the United States Constitution, as well as the New York State Constitution, guarantee Plaintiffs-Petitioners the right “to be secure in their persons... against unreasonable searches and seizures.”

71. It is a deprivation of the right to protection from an unreasonable seizure to force an injection by piercing the skin in order to inject a product that was licensed without inadequate clinical trials. It is an unreasonable seizure of one’s person and one’s naïve immune system when a parent’s informed decision – based on review of the existing literature regarding this product, their religious beliefs, and their intimate knowledge of their child, including the child’s medical and familial history – is to not inject their child with this product.

72. Threatening a violation and civil punishment upon the refusal to inject a product that a parent has not consented to, and one for which the unrebutted record reflects an increased risk of mortality, infringes upon Plaintiffs-Petitioners’ and their children’s right to freedom from unreasonable seizure.

C. Excessive Fines

73. Both the United States and New York Constitutions prohibit excessive fines.

74. The offense alleged here is the refusal of parents to inject their child with a product that a parent has not consented to, and one for which the record reflects will increase mortality, was not proven safe prior to licensure, and has numerous serious post-licensure adverse reactions. The mandate is not related to any privilege the parents or the children wish to enjoy; it is quite plainly a mandate for them to simply continue existing in their homes with their families. The civil penalty – here, a fine of \$1,000 – is a hefty one for Plaintiffs-Petitioners who are working-class families and generally live paycheck to paycheck. The fine bears no relationship to the gravity of the offense: existing in their homes without injecting their children.

D. Unenumerated Rights

75. The Ninth Amendment to the United States Constitution guarantees that “the enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.”

i. The Right to Privacy

76. One of those unenumerated rights retained by the people is the right to privacy. Plaintiffs-Petitioners were issued Summonses at their homes – some with police officers delivering them, others with Summonses taped to their doors for all to see – alleging a violation for a private choice made by their families or in consultation with their doctors or religious leaders.

77. The Commissioner’s Order and the Resolution invaded that privacy, made Plaintiffs-Petitioners’ children’s vaccination statuses widely known, and attempted to commandeer the private decisions of these families.

78. Violating Plaintiffs-Petitioners’ right to privacy in their medical and religious decisions is a violation of the Ninth Amendment.

ii. The Right to Informed Consent

79. Holding the Plaintiffs-Petitioners in violation for simply existing in their homes in the state in which they were born and for not injecting their children with a product that is not medically appropriate against their informed consent violates additional unenumerated constitutional rights, including the right to informed consent under the New York State Constitution and the United States Constitution. It further violates the long upheld constitutional rights to parental choice and bodily integrity under the New York State Constitution and the United States Constitution.

80. The United States Constitution and the New York State Constitution guarantee the right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

81. Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent to the medical procedure. Plaintiffs-Petitioners have reviewed the risks and benefits of the MMR and, based on that review and their intimate knowledge of their child, including their child's medical and family history, cannot consent to injecting this product into their children.

82. Threatening violations and civil penalties upon the refusal to inject a child with MMR where the child's parent has made an informed decision to not administer this product to their child infringes upon the well-established and valuable right to informed consent.

iii. The Right to Parental Choice

83. The United States Constitution and the New York State Constitution guarantee the recognized right to parental choice, which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

84. Coercing a parent to vaccinate their child by threatening violations and civil penalties upon the refusal to inject the MMR, where the child's parent has chosen to not administer this product to their child, infringes upon their protected right to parental choice.

iv. The Right to Bodily Integrity

85. The United States Constitution and the New York State Constitution guarantee the right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

86. Plaintiffs-Petitioners are each fully competent and able to make decisions based on the best interests of their child. Based on their intimate knowledge of their child, including their child's individual medical and familial histories, their religious beliefs, and their knowledge regarding the MMR, Plaintiffs-Petitioners and their children oppose injecting this product into their bodies.

87. Threatening violations and civil penalties by way of the Commissioner's Order and the Resolution conditioned upon the injection of MMR, when the child and the child's parents object to this injection, infringes upon the right to bodily integrity.

E. First Amendment Right to Free Exercise of Religion

88. The First Amendment to the United States Constitution unequivocally protects the right to the free exercise of religion. Likewise, the New York State Constitution provides that the free exercise of religion "shall forever be allowed in this state to all mankind."

89. The free exercise clauses recognize the right of each person to engage in the free exercise of his or her religion and not to be compelled to engage in affirmative acts which violate their religious beliefs. A key feature of this right is that it grants a religious individual an exemption from statutes or regulations which impose a burden on his or her beliefs.

90. Many of the Plaintiffs-Petitioners have sincerely held religious beliefs which prevent them from engaging in an act that they believe will harm their children.²⁴

91. The research has not yet been done to know which children are susceptible to be seriously injured or die from this product. Plaintiffs-Petitioners' informed assessment is that the risk of serious injury or death from this product to their child is greater than the risk of serious

²⁴ Plaintiffs-Petitioners that hold religious beliefs against vaccination are Plaintiffs-Petitioners Ascher Berkowitz, Chava Biederman, Israel Fishman, Judith Fried, Malka Friedman, Chanie Fulop, Rachel Guttman, Simon Josef, and Malky Roth-Tabak.

injury or death from measles and hence, administering this product to their child violates their religious beliefs.

92. At the time of the supposed violations, many of the Plaintiffs-Petitioners held statutorily protected religious exemptions from vaccinations from their children's schools.

93. Mandating an injection that directly contradicts Plaintiffs-Petitioners' religious beliefs is compelling them to act in a manner that plainly violates their right to freely exercise their religion; both the United States and the New York State Constitution protect Plaintiffs-Petitioners in refraining from an action that their religious beliefs prevent them from taking.

94. Indeed, Plaintiffs-Petitioners were held in violation for simply existing in their homes, with their families, in the state that God created them.

RELIEF REQUESTED

WHEREFORE, Plaintiffs-Petitioners request that this Court enter an Order:

(a) Declaring, pursuant to CPLR § 7803, that Defendant-Respondent acted arbitrarily, capriciously, and contrary to law by issuing its final determinations in the manner described herein;

(b) Declaring, pursuant to CPLR § 3001 and all other grounds by which a state act can be declared unconstitutional, that the Commissioner's Order and the Resolution violate the New York and United States Constitutions;

(c) Setting aside and vacating the Summonses;

(d) Awarding Plaintiffs-Petitioners reasonable attorney's fees, costs and disbursements pursuant to CPLR § 8101, 42 U.S.C.A. § 1983, any other applicable statutory, common law or equitable provision, and that any defense as to the validity of the Summonses is without merit; and

(e) Granting such other and further relief as the Court deems just and proper.

Dated: August 24, 2020

SIRI & GLIMSTAD LLP



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New York, New York 10166
Tel: (212) 531-1091
aaron@sirillp.com
ebrehm@sirillp.com

Counsel for Plaintiffs-Petitioners

VERIFICATION

STATE OF NEW YORK)
) ss:
COUNTY OF *Kings*)

Pursuant to CPLR § 3020, ISRAEL FISHMAN, being duly sworn, deposes and says:

I have read the foregoing petition and know the contents thereof as to ISRAEL FISHMAN and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.

Israel Fishman

Sworn to me this 24 day
of August, 2020

[Signature]

Notary Public



VERIFICATION

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

Pursuant to CPLR § 3020, Judith Fried, being duly sworn, deposes and says:

I have read the foregoing petition and know the contents thereof as to Judith Fried and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.

J. Fried
Judith Fried

Sworn to me this 22 day
of August, 2020
[Signature]
Notary Public

SOLOMON ITZKOWITZ
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 011T4795441
Qualified in Kings County
Commission Expires July 30, 2022

VERIFICATION

STATE OF NEW YORK)
) ss:
COUNTY OF)

Pursuant to CPLR § 3020, RACHEL GUTTMAN, being duly sworn, deposes and says:

I have read the foregoing petition and know the contents thereof as to RACHEL GUTTMAN and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.

Rachel Guttman

Sworn to me this 24th day
of August, 2020

[Signature]
Notary Public

PADRAM FEJAL
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01FE6305764
Qualified in Kings County
Commission Expires June 9, 2022

VERIFICATION

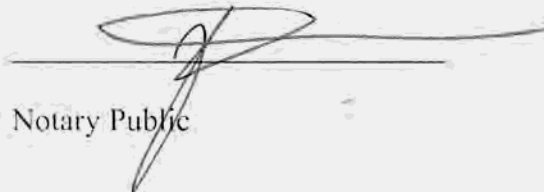
STATE OF NEW YORK)
) ss:
COUNTY OF)

Pursuant to CPLR § 3020, CHANIE FULOP, being duly sworn, deposes and says:

I have read the foregoing petition and know the contents thereof as to CHANIE FULOP and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.



Sworn to me this 20 day
of August, 2020


Notary Public

SOLOMON ITZKOWITZ
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 011T4795441
Qualified in Kings County
Commission Expires July 30, 2022

VERIFICATION

STATE OF NEW YORK)
) ss:
COUNTY OF Sullivan

Pursuant to CPLR § 3020, BAILA KLEIN, being duly sworn, deposes and says:

I have read the foregoing petition and know the contents thereof as to BAILA KLEIN and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.

Baila Klein

Sworn to me this 21st day
of August, 2020



Notary Public

ROSEMARIE LEE
Notary Public, State of New York
No. 01LE6018825
Qualified in Dutchess County
Commission Expires June 29, 2023

①

VERIFICATION

STATE OF NEW YORK)
) ss:
COUNTY OF)

Pursuant to CPLR § 3020, MALKY ROTH-TABAK, ^{(mb) affirms} ~~being duly sworn~~, deposes and says:

I have read the foregoing petition and know the contents thereof as to MALKY ROTH-TABAK and my minor child, that the same is true to my own knowledge, except as to matters therein alleged on information and belief, and that as to those matters I believe them to be true.

Malky Roth

^{(mb) Affirmed}
~~Sworn~~ to me this 24 day
of August, 2020

Jo Ann Beddoe
Notary Public

JO-ANN BEDDOE
NOTARY PUBLIC-STATE OF NEW YORK
No. 01BE6172751
Qualified in Queens County
My Commission Expires 08-13-2023

**SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK**

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

v.

Dept. of Health & Mental Hygiene of the City of New
York,

Defendant-Respondent.

**NOTICE OF VERIFIED
ARTICLE 78 AND
DECLARATORY JUDGMENT
PETITION**

PLEASE TAKE NOTICE, that upon the annexed Verified Article 78 and Declaratory Judgment Petition and Exhibits A through PP annexed thereto, the accompanying Memorandum of Law, and the accompanying Request for Judicial Intervention, Petitioners will move this Court at an Article 78 Term at the New York County Courthouse, 60 Centre Street, New York, on the 28th day of September, 2020 in the forenoon of that day, or as soon thereafter as counsel may be heard, for an order pursuant to Sections 7803, 3001, and 8101 of the New York Civil Practice Law and Rules (“CPLR”) and 42 U.S.C.A. § 1983:

- a) declaring, pursuant to CPLR § 7803, that Defendant-Respondent acted arbitrarily, capriciously, and contrary to law by issuing its final determinations in the manner described herein;
- b) declaring, pursuant to CPLR § 3001 and all other grounds by which a state act can be declared unconstitutional, that the Commissioner’s Order and the Resolution violate the New York and United States Constitutions;
- c) setting aside and vacating the Summonses;

- d) awarding Plaintiffs-Petitioners reasonable attorney's fees, costs and disbursements pursuant to CPLR § 8101, 42 U.S.C.A. § 1983, any other applicable statutory, common law or equitable provision, and that any defense as to the validity of the Summonses is without merit; and
- e) granting such other and further relief as the Court deems just and proper.

PLEASE TAKE FURTHER NOTICE that you must serve a verified answer, any supporting affidavits and documents, and a certified transcript of the record of proceedings at least five days before this application is made.

Plaintiff-Petitioner designates New York County as the place of trial. The basis of venue is because New York County is where material events giving rise to the petition took place; specifically, the OATH appellate decisions that are being challenged here were rendered in New York County.

Dated: August 24, 2020

SIRI & GLIMSTAD LLP



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**SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK**

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

v.

Dept. of Health & Mental Hygiene of the City of New
York,

Defendant-Respondent.

No. _____

**AFFIRMATION OF
ELIZABETH A. BREHM IN
SUPPORT OF VERIFIED
ARTICLE 78 AND
DECLARATORY JUDGMENT
PETITION**

Elizabeth A. Brehm, an attorney duly admitted to practice before the Courts of the State of New York and not a party to the above-captioned special proceeding, hereby affirms the following to be true, under penalty of perjury, pursuant to CPLR § 2106:

1. I am an attorney for the above captioned Plaintiffs-Petitioners.¹

2. All Exhibits referenced in the filed Verified Article 78 and Declaratory Judgment Petition and herein are exhibits admitted without objection at the OATH hearing or are otherwise part of the administrative record.

3. Attached as **Exhibit A** is a true and correct copy of Hearing Exhibit 39 – Physicians for Informed Consent, *Measles: What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

¹ Defined terms used herein shall have the meaning ascribed to them in the accompanying Verified Article 78 and Declaratory Judgment Petition.

4. Attached as **Exhibit B** is a true and correct copy of Hearing Exhibit 43 – CDC, *Vital Statistics of the United States, 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

5. Attached as **Exhibit C** is a true and correct copy of the Department of Health’s Hearing Exhibit 1, Commissioner’s Order (“Order”) dated April 9, 2019.

6. Attached as **Exhibit D** is a true and correct copy of *New York City Department of Mental Health and Hygiene v. Malky Roth Tabak*, Summons No. 30198-19LO hearing transcript dated August 28, 2019.

7. Attached as **Exhibit E** is a true and correct copy of the Department of Health’s Hearing Exhibit 2, *Resolution of the Board of Health of the Department of Health and Mental Hygiene of the City of New York*, adopted on April 17, 2019.

8. Attached as **Exhibit F** is a true and correct copy of the Summonses issued to Plaintiffs-Respondents.

9. Attached as **Exhibit G** is a true and correct copy of the OATH Appeal Decision for each Plaintiff-Petitioner, dated April 24, 2020.

10. Attached as **Exhibit H** is a true and correct copy of Hearing Exhibit 60, Declaration of Chava Biederman.

11. Attached as **Exhibit I** is a true and correct copy of Hearing Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

12. Attached as **Exhibit J** is a true and correct copy of Hearing Exhibit 28 – Allergologia et Immunopathologia, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

13. Attached as **Exhibit K** is a true and correct copy of Hearing Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

14. Attached as **Exhibit L** is a true and correct copy of Hearing Exhibit 20 – Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

15. Attached as **Exhibit M** is a true and correct copy of Hearing Exhibit 21 – Medical Hypotheses, *Febrile history infections of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

16. Attached as **Exhibit N** is a true and correct copy of Hearing Exhibit 22 – British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

17. Attached as **Exhibit O** is a true and correct copy of Hearing Exhibit 23 – NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

18. Attached as **Exhibit P** is a true and correct copy of Hearing Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

19. Attached as **Exhibit Q** is a true and correct copy of Hearing Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to*

chronic infections? (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

20. Attached as **Exhibit R** is a true and correct copy of Hearing Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

21. Attached as **Exhibit S** is a true and correct copy of Hearing Exhibit 18 – Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that having had measles and/or mumps significantly lowered the risk of mortality from cardiovascular disease).

22. Attached as **Exhibit T** is a true and correct copy of Hearing Exhibit 19 – CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

23. Attached as **Exhibit U** is a true and correct copy of Hearing Exhibit 20 – Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

24. Attached as **Exhibit V** is a true and correct copy of Hearing Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells (a line of human diploid cells), human albumin, bovine calf serum, and neomycin).

25. Attached as **Exhibit W** is a true and correct copy of Hearing Exhibit 13 – ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

26. Attached as **Exhibit X** is a true and correct copy of Hearing Exhibit 14 – ATTC, *WI-38* (describing that the WI-38 cell line was derived from a 3-month-old female fetus).

27. Attached as **Exhibit Y** is a true and correct copy of Hearing Exhibit 15 – The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

28. Attached as **Exhibit Z** is a true and correct copy of Hearing Exhibit 16 – Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

29. Attached as **Exhibit AA** is a true and correct copy of Hearing Exhibit 17 – Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

30. Attached as **Exhibit BB** is a true and correct copy of Hearing Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days) and Hearing Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses, among other adverse events, for trial participants).

31. Attached as **Exhibit CC** is a true and correct copy of the Declaration of Judith Fried.

32. Attached as **Exhibit DD** is a true and correct copy of Hearing Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* (“M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility”).

33. Attached as **Exhibit EE** is a true and correct copy of Hearing Exhibit 5 – Institute of Medicine (“**IOM**”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating a causal relationship between the rubella vaccine and chronic and acute arthritis).

34. Attached as **Exhibit FF** is a true and correct copy of Hearing Exhibit 6 – IOM, *Adverse Events Associated with Childhood Vaccines, 1994* (revealing that for 18 of 22 commonly reported adverse events following MMR, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events while the available science *did* show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

35. Attached as **Exhibit GG** is a true and correct copy of Hearing Exhibit 7 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that as late as 2012, the CDC had not conducted the science to determine if 23 of 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

36. Attached as **Exhibit HH** is a true and correct copy of Hearing Exhibit 8 – IOM, *Adverse Events Associated with Childhood Vaccines, 1994* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

37. Attached as **Exhibit II** is a true and correct copy of Hearing Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality, 2012* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

38. Attached as **Exhibit JJ** is a true and correct copy of Hearing Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017).

39. Attached as **Exhibit KK** is a true and correct copy of Hearing Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

40. Attached as **Exhibit LL** is a true and correct copy of Hearing Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

41. Attached as **Exhibit MM** is a true and correct copy of Hearing Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12- and 18-month MMR vaccination).

42. Attached as **Exhibit NN** is a true and correct copy of Hearing Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

43. Attached as **Exhibit OO** is a true and correct copy of Hearing Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

44. Attached as **Exhibit PP** is a true and correct copy of Hearing Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

45. Attached as **Exhibit QQ** is a true and correct copy of Hearing Exhibit 10 – Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

46. Attached as **Exhibit RR** is a true and correct copy of Hearing Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

47. Attached as **Exhibit SS** is a true and correct copy of Hearing Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

48. Attached as **Exhibit TT** is a true and correct copy of Hearing Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

49. Attached as **Exhibit UU** is a true and correct copy of Hearing Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles*

Vaccine in a Postelimination Environment (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

50. Attached as **Exhibit VV** is a true and correct copy of Hearing Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between not having had measles and the development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

51. Attached as **Exhibit WW** is a true and correct copy of Hearing Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination) *Electronic Support for Public Health – Vaccine Adverse Event Reporting System* by Harvard Pilgrim Health Care, Inc. (stating that “fewer than 1% of vaccine adverse events are reported.”).

52. Attached as **Exhibit XX** is a true and correct copy of Hearing Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

WHEREAS, Plaintiffs-Petitioners request that this Court enter an Order:

- a) declaring, pursuant to CPLR § 7803, that Respondent acted arbitrarily, capriciously, and contrary to law by issuing its final determinations in the manner described herein;
- b) declaring, pursuant to CPLR § 3001 and all other grounds by which a state act can be declared unconstitutional, that the Commissioner’s Order and the Resolution violate the New York and United States Constitutions;

- c) setting aside and vacating the Summonses;
- d) awarding Plaintiffs-Petitioners reasonable attorney's fees, costs and disbursements pursuant to CPLR § 8101, 42 U.S.C.A. § 1983, any other applicable statutory, common law or equitable provision, and that any defense as to the validity of the Summonses is without merit; and
- e) granting such other and further relief as the Court deems just and proper.

Dated: August 24, 2020



ELIZABETH A. BREHM

Exhibit A

MEASLES

What Parents Need to Know



P&C PHYSICIANS
FOR INFORMED
CONSENT

Available in Spanish at / Disponible en español en
physiciansforinformedconsent.org/measles



1. WHAT IS MEASLES?

Measles is a self-limiting childhood viral infection.

- Measles symptoms include a prodromal (initial) phase of cough, runny nose, eye irritation and fever, followed by a generalized rash on days 4–10 of the illness.¹
- Measles is contagious during the prodromal phase and for 3-4 days after rash onset.¹
- Most measles cases are benign and not reported to public health departments.²
- Before the measles mass vaccination program was introduced, nearly everyone contracted measles and obtained lifetime immunity by age 15.¹
- In rare situations, measles can cause brain damage and death.^{3,4}

Centers for Disease Control and Prevention (CDC) publishes measles case-fatality rates based on reported cases. However, nearly 90% of measles cases are benign and not reported to the CDC.² Calculating case-fatality rates based on reported cases (that constitute only 10% of all cases) results in a case-fatality rate that is 10 times higher than what it actually is in the general population. Data analysis herein is based on total measles cases (both reported and unreported).



2. WHAT ARE THE RISKS?

In the modern era, it is rare to suffer permanent disability or death from measles in the United States. Between 1900 and 1963, the mortality rate of measles dropped from 13.3 per 100,000 to 0.2 per 100,000 in the population, due to advancements in living conditions, nutrition, and health care—a 98% decline (Fig. 1).^{2,5} Malnutrition, especially vitamin A deficiency, is a primary cause of about 90,000 measles deaths annually in underdeveloped nations.⁶ In the U.S. and other developed countries, 75–92% of hospitalized measles cases are low in vitamin A.^{7,8}

Research studies and national tracking of measles have documented the following:

- 1 in 10,000 or 0.01% of measles cases are fatal.³
- 3 to 3.5 in 10,000 or 0.03–0.035% of measles cases result in seizure.⁹
- 1 in 20,000 or 0.005% of measles cases result in measles encephalitis.⁴
- 1 in 80,000 or 0.00125% of cases result in permanent disability from measles encephalitis.⁴
- 7 in 1,000 or 0.7% of cases are hospitalized.¹⁰
- 6 to 22 in 1,000,000 or 0.0006–0.0022% of cases result in subacute sclerosing pan-encephalitis (SSPE).¹¹

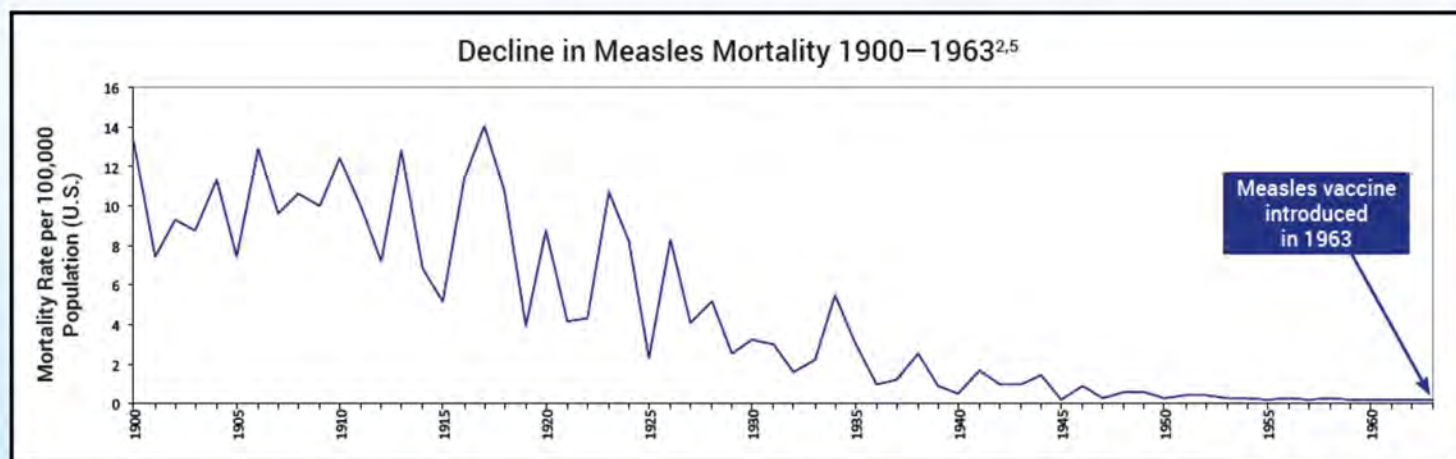


Figure 1: Measles death declined 98% from 1900 to 1963, before the measles vaccine was introduced.



3. WHAT TREATMENTS ARE AVAILABLE FOR MEASLES?

Because measles resolves on its own in almost all cases, usually only supportive treatment is necessary. As such, treatment options include the following:

- Rest
- Hydration
- High-dose vitamin A¹²
- Immune globulin (available for immunocompromised patients, such as those on chemotherapy)¹³



Vitamin A

The World Health Organization (WHO) recommends that serious measles cases be treated with high-dose vitamin A, 50,000–200,000 IU, orally on two consecutive days.¹³



4. ARE THERE ANY BENEFITS FROM GETTING MEASLES?

There are studies that suggest a link between naturally acquired measles infection and a reduced risk of Hodgkin's and non-Hodgkin's lymphomas, as well

as a reduced risk of atopic diseases such as hay fever, eczema and asthma.¹⁴⁻¹⁸ In addition, measles infections are associated with a lower risk of mortality from cardiovascular disease in adulthood.¹⁹ Moreover, infants born to mothers who have had naturally acquired measles are protected from measles via maternal immunity longer than infants born to vaccinated mothers.²⁰



5. WHAT ABOUT THE VACCINE FOR MEASLES?

The measles vaccine was introduced in the U.S. in 1963 and is now only available as a component of the measles, mumps, and rubella (MMR) vaccine. It has significantly reduced the incidence of measles; however, the vaccine is not capable of preventing all cases of measles, as failures have been reported.²¹ The manufacturer's package insert contains information about vaccine ingredients, adverse reactions, and vaccine evaluations. For example, "M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility."¹¹ Furthermore, the risk of permanent injury and death from the MMR vaccine has not been proven to be less than that of measles (Fig. 2).^{22,23}

Measles Mortality vs. Leading Causes of Death in Children Under Age 10 (per 100,000 Population)²²⁻²⁵

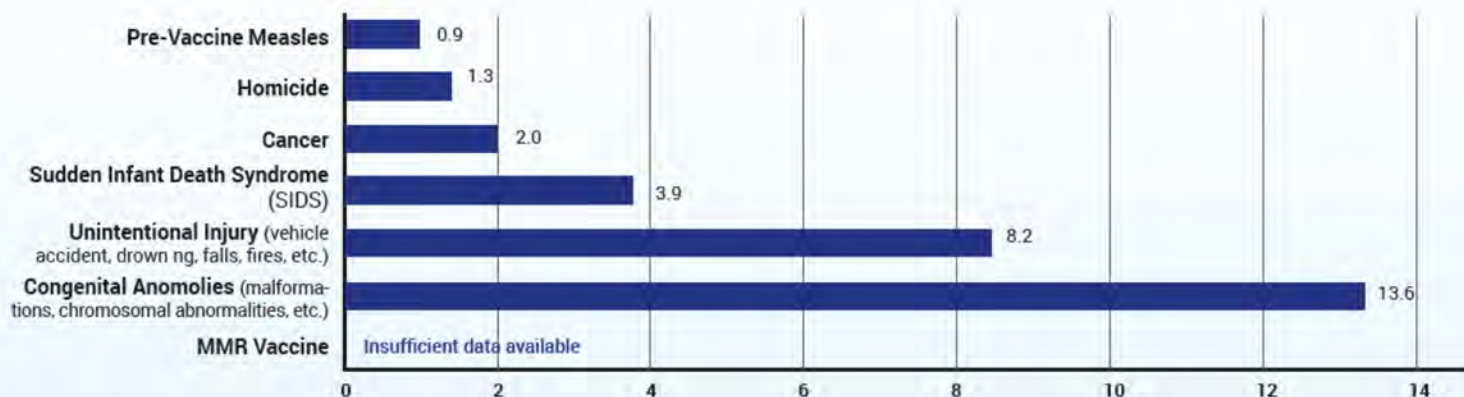


Figure 2: This graph shows the measles death rate before the vaccine was introduced, when measles was a common childhood viral infection, and compares it to the leading causes of death in children under age 10 today. Hence, in the pre-vaccine era, the measles death rate per 100,000 was 0.9 for children under age 10. In 2015, the death rate per 100,000 for homicide was 1.3, followed by cancer (2.0), SIDS (3.9), unintentional injury (8.2), and congenital anomalies (13.6). The rate of death or permanent injury from the MMR vaccine is unknown because the research studies available are not able to measure it with sufficient accuracy.^{22,23}

All references and the Measles Vaccine Risk Statement (VRS) are available at physiciansforinformedconsent.org/measles.

These statements are intended for informational purposes only and should not be construed as personal medical advice.

REFERENCES

1. Centers for Disease Control. Epidemiology and prevention of vaccine-preventable diseases. 13th ed. Hamborsky J, Kroger A, Wolfe S, editors. Washington D.C.: Public Health Foundation; 2015. 209-15.
2. **Between 1959 and 1962, annually there were about 4 million cases, of which 440,000 (11%) were reported.**
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surveillance in the 1980s and 1990s showed that there
if as many cases of measles encephalitis as there are

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n with severe measles. N Engl J Med. 1990 July;323(3):160-4.

es surveillance in the 1980s and 1990s showed that there
to 3.5 times more measles seizures than measles deaths (3
per 10,000 cases).

the sources as references 1 and 3.

les surveillance in the 1980s and 1990s showed that there
about 70 times more measles hospitalizations than measles
ths (7 per 1,000 cases).

Same sources as reference 3.

- Centers for Disease Control. Current trends measles – United States, 1989 and first 20 weeks 1990, June 1990. MMWR. 1990;39(21):353-5,361-3.

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Exhibit B

VITAL STATISTICS RATES
IN THE
UNITED STATES
1940-1960

By
Robert D. Grove, Ph. D.
and
Alice M. Hetzel

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Washington, D.C. 1968
National Center for Health Statistics

NATIONAL CENTER FOR HEALTH STATISTICS

THEODORE D. WOOLSEY, *Director*
PHILIP S. LAWRENCE, Sc. D., *Associate Director*
OSWALD K. SAGEN, Ph. D., *Assistant Director for Health Statistics
Development*
WALT R. SIMMONS, M.A., *Assistant Director for Research
and Scientific Development*
ALICE M. WATERHOUSE, M.D., *Medical Consultant*
JAMES E. KELLY, D.D.S., *Dental Advisor*
EDWARD E. MINTY, *Executive Officer*
MARGERY R. CUNNINGHAM, *Information Officer*

Division of Vital Statistics

ROBERT D. GROVE, Ph. D., *Director*
ROBERT A. ISRAEL, M.S., *Deputy Director*
ROBERT A. ISRAEL, M.S., *Acting Chief, Mortality Statistics Branch*
JOHN E. PATTERSON, *Chief, Natality Statistics Branch*
LOREN E. CHANCELLOR, *Chief, Registration Methods Branch*
ALICE M. HETZEL, *Chief, Marriage and Divorce Statistics Branch*
ARNE B. NELSON, M.A., *Chief, Vital Records Survey Branch*
MICHAEL J. ZUGZDA, *Acting Chief, Statistical Resources Section*

Public Health Service Publication No. 1677

CHARTS

Figure 19.—Death Rates for Measles: Death-registration States, 1900–32, and United States, 1933–60

(Rates per 100,000 population).

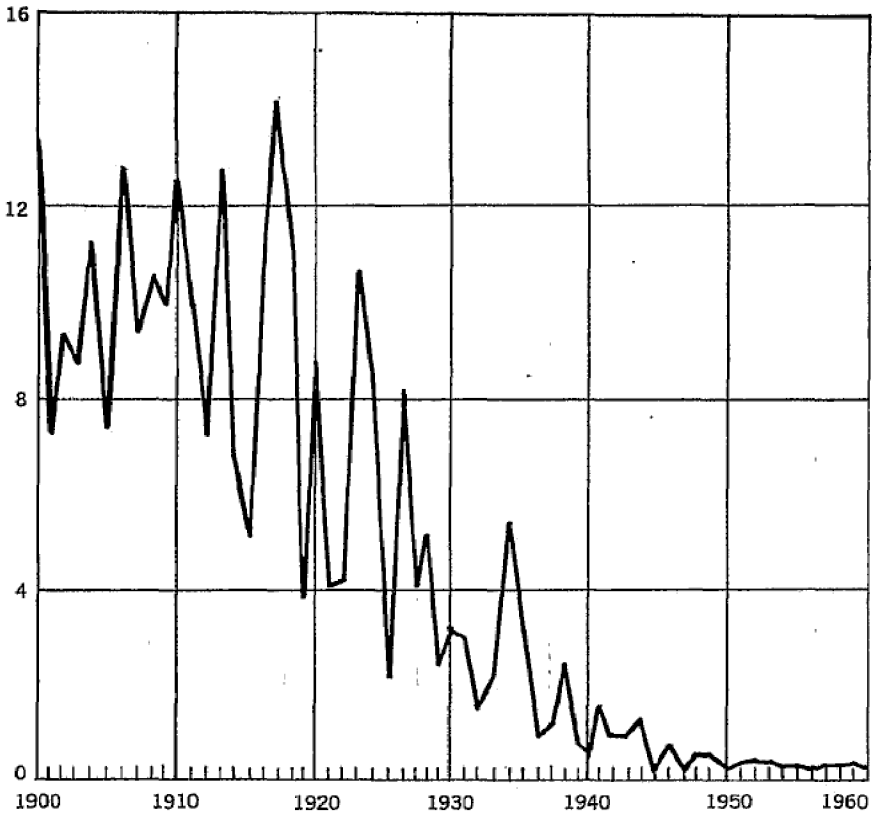


TABLE 65.—Death rates for detailed causes: Death-registration States, 1900-1932, and United States, 1933-80

Section A, 1900-1909

[Rates are deaths per 100,000 population. Numbers before causes of death are category numbers of First Revision of the International Lists]

Int. List No.	Cause of death	1900	1901	1902	1903	1904	1905	1906	1907	1908	1909
	All causes.....	1,719.1	1,641.5	1,548.1	1,562.8	1,640.0	1,588.9	1,571.8	1,562.5	1,468.2	1,424.7
	I.—General diseases.....	466.5	456.0	412.2	421.4	430.1	408.2	412.6	416.3	391.5	372.3
1	Typhoid fever (abdominal typhus).....	31.3	27.6	26.4	24.6	23.9	22.4	30.9	28.2	23.4	20.2
2	Exanthematic typhus.....	0.0	—	0.0	—	0.0	0.0	—	0.0	—	0.0
3	Relapsing fever.....	0.0	0.0	0.0	0.0	0.0	—	0.0	—	0.0	—
4	Intermittent fever and malarial cachexia.....	6.2	5.0	4.0	3.0	2.9	2.5	2.3	1.8	1.3	1.4
5	Smallpox.....	0.3	3.6	6.5	1.5	0.8	0.6	0.2	0.1	0.2	0.1
6	Measles.....	13.3	7.4	9.3	8.8	11.3	7.4	12.9	9.6	10.6	10.0
7	Scarlet fever.....	9.6	13.6	11.9	12.3	11.6	6.8	7.3	9.3	12.4	11.1
8	Whooping cough.....	12.2	8.7	12.4	14.3	5.8	8.9	16.1	11.3	10.7	10.0
9	Diphtheria and croup.....	40.3	33.5	29.8	31.1	29.3	23.5	26.3	24.2	21.9	19.9
10	Influenza.....	25.7	36.5	10.4	19.2	21.8	20.5	10.2	25.0	21.1	13.3
11	Military fever.....	—	—	0.0	0.0	0.0	—	—	—	0.0	—
12	Asiatic cholera.....	—	—	—	—	—	—	—	—	—	—
13	Cholera nostras.....	2.8	1.8	1.4	1.2	1.2	1.4	1.4	1.0	1.1	0.8
14	Dysentery.....	12.0	11.1	10.1	7.3	8.1	8.3	8.0	6.1	6.1	5.4
15	Bubonic plague.....	—	0.0	—	—	—	—	—	0.2	0.0	0.0
16	Yellow fever.....	0.0	—	0.0	—	—	0.0	—	—	—	—
17	Leprosy.....	—	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
18	Erysipelas.....	5.4	4.5	4.1	4.0	5.1	4.7	4.3	4.4	3.8	3.9
19	Other epidemic diseases.....	0.2	0.1	0.2	0.2	0.2	0.2	0.4	0.3	0.3	0.3
20	Purulent infection and septicemia.....	7.2	5.9	5.9	4.7	4.9	4.4	3.8	3.7	3.2	2.9
21	Glanders and farcy.....	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
22	Malignant pustule.....	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0
23	Rabies.....	0.1	0.1	0.1	0.1	0.0	0.1	0.2	0.2	0.2	0.1
24	Actinomyces, trichinosis, etc.....	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1
25	Pellagra.....	0.0	—	—	0.0	—	—	—	—	—	0.0
	Tuberculosis (all forms).....	194.4	189.0	174.2	177.2	188.1	179.9	175.8	174.2	162.1	156.3
26	Tuberculosis of the larynx.....	1.2	1.6	1.6	1.5	1.6	1.6	1.5	1.6	1.5	1.6
27	Tuberculosis of the lungs.....	173.3	167.9	152.8	164.2	164.2	155.5	151.8	150.4	138.6	133.3
28	Tuberculosis of the meninges.....	9.4	9.1	9.3	9.6	9.8	9.9	9.8	9.8	9.4	9.1
29	Abdominal tuberculosis.....	4.9	5.4	5.1	5.2	5.8	5.3	6.0	5.8	5.7	5.9
30	Pott's disease.....	1.5	1.4	1.4	1.5	1.6	1.6	1.5	1.4	1.6	1.4
31	Cold abscess, abscess by congestion.....	0.1	0.1	0.1	0.2	0.2	0.2	0.1	0.2	0.2	0.1
32	White swelling.....	0.6	0.6	0.6	0.6	0.7	0.8	0.8	0.6	0.8	0.7
33	Tuberculosis of other organs.....	1.0	1.2	1.1	1.4	1.6	1.5	1.6	1.6	1.7	1.7
34	General tuberculosis.....	2.3	2.7	2.4	3.0	2.7	3.0	2.6	2.8	2.8	2.3

TABLE 65.—Death rates for detailed causes: Death-registration States, 1900-1932, and United States, 1933-60—Continued
Section F, 1949-1960—Continued

Cause of death	1940	1950	1951	1952	1953	1954	1955	1956	1957	1958	1959	1960
I.—Infective and parasitic diseases—Continued												
Syphilis and its sequelae—Continued												
Other syphilis of central nervous system.....026	0.6	0.5	0.5	0.4	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.1
All other syphilis.....027-029	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0
Gonococcal infection.....030-035	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Typhoid fever.....040	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paratyphoid fever and other Salmonella infections.....041, 042	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cholera.....043	—	—	—	—	—	—	—	—	—	—	—	—
Brucellosis (undulant fever).....044	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Dysentery, all forms.....045-048	1.0	0.6	0.7	0.6	0.6	0.4	0.3	0.3	0.3	0.2	0.2	0.2
Food poisoning (infection and intoxication).....049	6.2	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0
Scarlet fever.....050	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Streptococcal sore throat.....051	0.3	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Erysipelas.....052	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Septicemia and pyemia.....053	0.4	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.8	1.0	1.0	1.1
Diphtheria.....055	0.4	0.3	0.2	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0
Whooping cough.....056	0.5	0.7	0.6	0.3	0.2	0.2	0.3	0.2	0.1	0.1	0.2	0.1
Meningococcal infections.....057	0.6	0.3	0.7	0.9	0.8	0.6	0.6	0.5	0.5	0.4	0.4	0.4
Plague.....058	0.0	0.0	0.0	—	—	—	—	0.0	—	—	0.0	—
Leprosy.....060	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tetanus.....061	0.3	0.2	0.3	0.2	0.2	0.2	0.2	0.1	0.2	0.2	0.2	0.1
Anthrax.....062	—	0.0	0.0	0.0	—	—	—	—	0.0	0.0	—	—
Acute poliomyelitis.....080	1.8	1.3	1.0	2.0	0.9	0.8	0.6	0.3	0.1	0.1	0.3	0.1
Late effects of acute poliomyelitis.....081	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Acute infectious encephalitis.....082	0.3	0.3	0.3	0.3	0.2	0.3	0.2	0.3	0.3	0.3	0.3	0.3
Late effects of acute infectious encephalitis.....083	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0
Smallpox.....084	0.0	0.0	0.0	—	0.0	—	—	—	—	—	—	—
Measles.....085	0.6	0.3	0.4	0.4	0.3	0.3	0.2	0.3	0.2	0.3	0.2	0.2
Yellow fever.....091	—	—	—	—	—	—	—	—	—	—	—	—
Infectious hepatitis.....092	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Rabies.....094	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tick-borne typhus.....104	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Typhus, other and unspecified, and other Rickettsial diseases.....100-103, 105-108	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	—
Malaria.....110-117	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Schistosomiasis.....123	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Hydatid disease.....125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Filariasis.....127	0.0	0.0	—	0.0	—	—	—	—	—	—	—	—
Ancylostomiasis.....129	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	—	0.0	0.0	—
Other diseases due to helminths.....124, 126, 128, 130	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
All other infective and parasitic diseases.....036-039, 054, 059, 063-074, 086-090, 093, 095, 096, 120-122, 131-138	0.7	0.7	0.8	0.8	0.8	0.7	0.7	0.8	0.7	0.7	0.8	0.8

Exhibit C



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, M.D.
Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

Exhibit D

NYC OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS

COUNTY OF NEW YORK

- - - - - x

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL

HYGIENE,

Petitioner,

Summons No. 30198-19L0

-against-

MALKY ROTH TABAK,

Respondent.

- - - - - x.

66 John Street
New York, New York

August 28, 2019
10:11 a.m.

B E F O R E:

HONORABLE DAVID LEUNG.

1 A P P E A R A N C E S:

2 General Counsel,
3 NYC Department of Health and Hygiene

4 BY: THOMAS MERRILL, ESQ.
5 LORAIN PEONE, ESQ.

6 AARON SIRI, ESQ.
7 ATTORNEY for the Respondent
8 200 Park Avenue, 17th Floor
9 New York, New York

10 ALSO PRESENT:

11 Dr. Jennifer Rosen
12 Joseph Russo

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1 MR. LEUNG: Okay. We are on
2 the record. The recording has begun.
3 My name is David Leung, Hearing
4 Officer. It's August 28th, 2019,
5 10:11 in the morning. We are here
6 today on the Health Department Issue
7 Summons Complaint No. 30198-19L0 --
8 or is that L0 -- it looks like L0 --
9 issued to Malky Tabak at 585 Marcy
10 Avenue, apartment 2A.

11 We have attorneys and
12 representatives from the Department
13 of Health. Can you put your name on
14 the record and spell it, please.

15 MR. MERRILL: The Department of
16 Health, Thomas Merrill,
17 M-E-R-R-I-L-L.

18 MR. LEUNG: And who else is
19 here from the Department of Health?

20 MS. PEONE: Loraine Peone,
21 L-O-R-A-I-N-E P-E-O-N-E, attorney for
22 the Department of Health.

23 MR. LEUNG: Okay. Mr. Merrill,
24 what is your position with the DOH?

25 MR. MERRILL: I am the general

1 counsel.

2 MR. LEUNG: General counsel.

3 Okay. And who else who else is here
4 from the Department of Health?

5 MS. ROSEN: Jennifer Rosen,
6 R-O-S-E-N.

7 MR. LEUNG: And what is your
8 position with the DOH?

9 MS. ROSEN: Physician at the
10 Department of Health.

11 MR. LEUNG: Physician. Okay.

12 MR. RUSSO: And Joseph Russo,
13 R-U-S-S-O, paralegal, observing.

14 MR. LEUNG: Okay. And for the
15 Respondent?

16 MR. SIRI: Good morning, your
17 Honor, Aaron Siri, A-A-R-O-N S-I-R-I.

18 MR. LEUNG: Okay.

19 MR. SIRI: Is it okay --

20 MR. LEUNG: Go ahead.

21 MR. SIRI: Is it okay if we
22 take up some of your real estate?

23 MR. LEUNG: Absolutely.

24 MR. SIRI: I just want to make
25 sure.

1 MR. LEUNG: No, no, thank you.
2 Make sure you use whatever space you
3 need.

4 Counsel, do you swear the
5 testimony you will give will be the
6 truth? Okay. Thank you.

7 Mr. Siri, I have to -- I am
8 going to go over these rights, and
9 for all of the hearings that follow,
10 if you will, just -- just to save --
11 you have a right to have an
12 interpreter. You don't need one; is
13 that correct?

14 MR. SIRI: That's right.

15 MR. LEUNG: And do you waive
16 the need to have the actual officer
17 or inspector that wrote the ticket
18 appear at the hearing?

19 You have a right to have that
20 inspector present to cross examine
21 him or her.

22 MR. SIRI: No, I don't.

23 MR. LEUNG: So you are okay to
24 proceed without the inspector?

25 MR. MERRILL: No, I don't waive

1 the right.

2 MR. LEUNG: Okay. You don't
3 waive the right. Okay. Are you
4 demanding the presence of the issuing
5 officer?

6 MR. SIRI: Yes.

7 MR. LEUNG: Who is the issuing
8 officer on this summons -- I mean the
9 inspector?

10 (Indiscernible.)

11 MR. LEUNG: Counsel, I am going
12 to ask you to put on the record the
13 basis for requesting the issuing
14 officer.

15 MR. SIRI: Sure. In this
16 summons, your Honor, it says the
17 issuing officer is the one that
18 swears the accuracy of the violation.

19 MR. LEUNG: Right.

20 MR. SIRI: The violation
21 claims, under penalty of perjury,
22 that Respondent has failed to
23 vaccinate child, C.R., and otherwise
24 to admit acceptable proof of immunity
25 in violation of the order.

1 I believe that the issuing
2 officer should be able to -- should
3 be here to explain how they arrived
4 at the definitive conclusion that the
5 Respondent didn't submit acceptable
6 proof of immunity.

7 Was Respondent requested to
8 submit the proof of immunity?

9 MR. LEUNG: Okay. Let me just
10 -- let me just --

11 MR. SIRI: Yeah.

12 MR. LEUNG: What happens is you
13 have under oath rules, hearing rules,
14 you have a right to ask that the
15 hearing officer appear, I have to
16 make a determination as to whether --

17 MR. SIRI: I understand.

18 MR. LEUNG: -- as to whether the
19 issuing officer's appearance is
20 necessary for you, as the Respondent,
21 to get a fair hearing, so I am going
22 to turn to the Petitioner.

23 Counsel for Respondent has made
24 an application to request that the
25 issuing officer appear on the basis

1 of -- and if I summarize it
2 incorrectly, let me know -- that the
3 sworn allegations are made out by the
4 issuing officer and that you believe
5 that you should have an opportunity
6 to cross examine him or her as to the
7 basis --

8 MR. SIRI: Her.

9 MR. LEUNG: -- her as to the
10 basis of how she made the allegations
11 as written in the summons; is that
12 correct?

13 MR. SIRI: Yes, including that
14 it was, you know, including regarding
15 the medical appropriateness to
16 provide this injection, as well as,
17 as I said, the DOH violation.

18 Yeah, I am going to leave it at
19 that.

20 MR. LEUNG: Okay.

21 MR. SIRI: We will get into
22 specifics if you want.

23 MR. LEUNG: Right. I am going
24 to turn it over to DOH and ask you to
25 respond as to the --

1 MR. MERRILL: Sure, your Honor.

2 So I don't believe -- I think
3 that anything that the Petitioner
4 wants -- or the Respondent wants, Dr.
5 Rosen is here to explain.

6 The allegations were -- the
7 NOVs were issued based on the DOH --
8 there was an order that he be
9 immunized.

10 The allegations were issued --
11 excuse me -- the NOV was issued after
12 the check of the official records for
13 vaccinations was done and I think Dr.
14 Rosen can testify about that as well.

15 Dr. Rosen can also testify
16 about the various terms, in reaching
17 out for contact, and in terms of
18 explaining the medical necessity of
19 the vaccine. She is more capable of
20 doing that.

21 MR. LEUNG: And, Mr. Siri, how
22 do you respond to that?

23 MR. SIRI: Well, it's about the
24 medical appropriateness for this
25 particular respondent.

1 MR. LEUNG: Okay.

2 MR. SIRI: Not vaccines in
3 general, right? Like every drug, not
4 everybody can have penicillin.

5 MR. LEUNG: Do you want the
6 testimony to reflect what she put
7 down in the -- you are saying that
8 you want to put the inspector to the
9 burden of proving how she alleged
10 what she alleged?

11 MR. SIRI: Right. I mean she
12 -- she, you know, under this
13 violation, she says that my client
14 did not submit acceptable proof of
15 immunity.

16 I believe that the, you know,
17 the issuing officer who swore to that
18 should be able to substantiate, for
19 example, was that ever requested and
20 how did she determine that there was
21 no acceptable proof of immunity.

22 And, also, that the, again, and
23 most importantly, I think, is that it
24 was medically appropriate for this
25 child to be immunized.

1 MR. LEUNG: I am going to turn
2 to the Department of Health.

3 Was this allegation failure to
4 comply?

5 MR. MERRILL: Failure to be
6 immunized.

7 MR. LEUNG: Failure to be
8 immunized?

9 MR. MERRILL: Yeah, failure to
10 be immunized that was issued to
11 residents of Williamsburg.

12 MR. LEUNG: So failure to
13 comply with the Commissioner's --

14 MR. MERRILL: Correct.
15 Correct.

16 If the child had been
17 immunized, that would have been in
18 the immunity -- in the immunization
19 registry.

20 That is something that
21 maintained and that, again, Ms.
22 Kaplan checked and which Dr. Rosen
23 checked -- or will testify about.

24 In terms of the medical
25 necessity, the matter of the fact is

1 that, you know, the vaccine is safe
2 and medically appropriate for the
3 vast majority of people.

4 When there are, you know, rare
5 instances, medical exemptions or
6 physicians may say that an
7 immunization is medically
8 inappropriate, they reach out, we do
9 review, we are doing that for a
10 couple of other clients.

11 There has been no indication
12 that this particular child has one of
13 the rare conditions that makes this
14 vaccine inappropriate for this child.

15 MR. LEUNG: Okay. Mr. Siri?

16 MR. SIRI: I agree that the
17 vast majority of people receive this
18 -- the MMR product that they are
19 demanding. It's true. Most --

20 MR. LEUNG: What we are going
21 to do -- I think we are going into
22 the facts of the case, which I --
23 this is just a preliminary ruling.
24 You have made an application to
25 request that the issuing officer

1 appear.

2 Before we begin the hearing, I
3 have to address this hurdle.

4 MR. SIRI: I understand.

5 MR. LEUNG: And I have to make
6 a ruling. That's why I am giving you
7 an application.

8 And, Counsel, based upon --
9 first off, I am just going -- under
10 oath, trial and hearing rules,
11 hearsay is permissible. It's really
12 liberal. You can have triple and
13 double hearsay. It's really liberal.

14 So the necessity of an issuing
15 officer, the reason why I asked you
16 for the application is that you have
17 to make a good cause showing that the
18 issuing officer is required to appear
19 in order for you to get a fair and
20 impartial hearing.

21 In other words, nothing that
22 any of these parties that are here
23 today, including counsel for DOH, you
24 need to argue and establish, can
25 substitute for the in-person

1 testimony of the issuing officer.

2 That's why I asked you to make the
3 application.

4 Based upon hearing both sides,
5 I am going to rule that the hearing
6 today to go forward. In other words,
7 that the -- I am going to rule that
8 the issuing officer is not required
9 for you to get a fair hearing because
10 what she wrote on the -- on the
11 summons is -- again, and the rule is
12 established on -- in other words, we
13 have people here to present a case
14 and you can make an argument and
15 testify on behalf of your client and
16 make arguments or call witnesses to
17 --

18 (Indiscernible.)

19 So I am going to make a ruling
20 that the issuing officer is not
21 required for you to get a fair and
22 impartial hearing.

23 I am going to give you one
24 additional opportunity to -- because
25 you look perplexed as to why --

1 MR. SIRI: No, no, I
2 understand.

3 MR. LEUNG: No, no, but that's
4 the standard, which is --

5 MR. SIRI: I understand --

6 MR. LEUNG: -- the inability of
7 your client and yourself to get a
8 fair and impartial hearing.

9 Is there anything that you wish
10 to add or supplement in the
11 application that you have made?

12 MR. SIRI: Yeah. Just my, you
13 know, my -- I -- I think I made my
14 arguments on the record and I just
15 stand with those.

16 MR. LEUNG: Okay. Okay. No
17 problem.

18 MR. SIRI: I think the hearing
19 officer was necessary to establish
20 medical appropriateness, but I
21 understand, your Honor, so...

22 MR. LEUNG: Okay.

23 MR. MERRILL: I would like to
24 add one thing, your Honor.

25 MR. LEUNG: Sure.

1 MR. MERRILL: Along with the
2 NOV, there was a frequently asked
3 question that served as well on
4 everyone in that order.

5 And in that, there were
6 questions and answers about, you
7 know, submitting proof of immunity or
8 proof of a medical exemption, and we
9 have not received any of these -- we
10 certainly cannot --

11 MR. SIRI: I believe, your
12 Honor, that it's the, you know, that
13 that should have been done before the
14 violation -- meaning the violation is
15 issued. If it's not medically
16 appropriate, it should have been
17 established or determined before the
18 before the violation was issued.

19 Also, it is not as simple as,
20 you know, going to good doctors,
21 getting genetic testing, getting
22 various -- doing the type of work
23 that's sometimes required. My burden
24 is it's not as simple as just
25 submitting a piece of paper.

1 MR. LEUNG: Mr. Siri, before we
2 get into the meat of the hearing --

3 MR. SIRI: Yes.

4 MR. LEUNG: -- there is a couple
5 of other things, and this gets
6 tedious, but I have to advise you the
7 penalty of this sole charge, if you
8 are found in violation, is \$1,000.

9 MR. SIRI: My client's dollars.

10 MR. LEUNG: \$1,000 for your
11 client, right.

12 If you are -- when I say "you",
13 I mean the Respondent. I'm sorry.

14 MR. SIRI: Yes. No problem.

15 MR. LEUNG: And I need to
16 advise you that if you disagree with
17 my written decision, which you will
18 get within 30 days, you have a right
19 to appeal my decision.

20 And if I dismiss the summons or
21 reduce it in any way, the Department
22 of Health has an equal right to
23 appeal my decision if they disagree
24 with it, okay, sir?

25 MR. SIRI: Yes.

1 MR. LEUNG: All right. We are
2 going to get to the meat of the
3 hearing. Let me just -- okay.

4 The summons alleges that on
5 April 21st, 2019, at 9:00 in the
6 morning, during an inspection that
7 occurred at 585 Marcy Avenue,
8 apartment 2E, Brooklyn, New York, a
9 violation of New York City Health
10 Code 3.05, the penalty for this
11 violation is found in violation of
12 \$1,000.

13 The inspector wrote, in
14 response, the act of measles outbreak
15 in certain parts of Brooklyn, the New
16 York City Commissioner of Health
17 declared a public health emergency on
18 April 9th, 2019 and it published the
19 commissioner's order pursuant to
20 Article 3 of the New York City Health
21 Code ordering all persons who live,
22 work, or attend school within zip
23 codes 11205, 11206, 11211, and 11249
24 to be vaccinated against measles
25 within 48 hours of the order.

1 On April 17th 2019, a New York
2 City Board of Health unanimously
3 approved the resolution to the health
4 -- the public health emergency and
5 requirement that all persons living,
6 working, or attending school in these
7 affected zip codes be vaccinated.

8 The resolution further provides
9 that any person that is not
10 vaccinated or any parent and/or
11 guardian of the child who is not
12 vaccinated shall be fined unless they
13 demonstrate proof of immunity or that
14 the immunization is not medically
15 appropriate.

16 A copy of the order and
17 resolution are attached to this
18 summons for reference.

19 A review of Department of
20 Records shows that Respondent, child,
21 C.R., who is at least 6-months-old,
22 lives at 585 Marcy Avenue, apartment
23 2E, Brooklyn, New York 11216, which
24 is located in one of the affected zip
25 codes listed in the order.

1 On April 21st, 2019, a review
2 of the department's central
3 immunization registry, which collects
4 immunization records for all children
5 receiving vaccines in New York City
6 and is required to be updated by
7 medical providers, found the child
8 here has no record of measles
9 immunization. Respondent failed to
10 vaccinate child, C.R., or otherwise
11 submit acceptable proof of immunity
12 in violation of the order.

13 I am going to first turn to the
14 Department of Health and ask if they
15 have any documents or evidence that
16 you want to present.

17 MR. MERRILL: Yes, your Honor,
18 I have in my file -- I apologize --
19 but I have a copy of the order of the
20 Commissioner, which was issued on
21 April 9th --

22 (Indiscernible.)

23 MR. MERRILL: I also have, for
24 the record, as a reference, the Board
25 of Health resolution dated

1 April 17th, and this is --

2 MR. LEUNG: Okay. I am going
3 to mark the Commissioner's order as
4 Petitioner's 1 and the Board's
5 resolution as Petitioner's 2.

6 I am going to show them to Mr.
7 Siri and ask do you have any
8 objections to those being submitted
9 into evidence?

10 MR. SIRI: I have no objection
11 other than -- I have no objection,
12 your Honor.

13 MR. LEUNG: Okay. Those are
14 admitted into evidence.

15 (Whereupon, two documents were
16 marked individually as Petitioner's
17 Exhibits 1 and 2, for identification, as
18 of this date.)

19 MR. LEUNG: Anything else from
20 the Department of Health?

21 MR. MERRILL: In terms of
22 documents, no, your Honor.

23 MR. LEUNG: Okay. Do you have
24 any testimony that you want to
25 provide?

1 MR. MERRILL: Yes.

2 You know, again, this was --
3 the order was issued on April 9th
4 directing all residents, children who
5 live, go to school, that reside in
6 Williamsburg, be immunized.

7 After a case investigation,
8 this -- the registry, which has a
9 record of all vaccinations of
10 children in the city, was checked on
11 April 19th, and the Respondent's
12 child was found not to be vaccinated.

13 The NOV was issued and found
14 not submitted any proof or records of
15 immunity, there is no record for
16 medical exemption, the child's state
17 remains unvaccinated.

18 (Indiscernible.)

19 MR. LEUNG: Okay. Is that all
20 of the evidence that you are going to
21 present?

22 MR. MERRILL: Yes.

23 MR. LEUNG: Okay. Sir, do you
24 have any cross examination before we
25 present your argument or evidence?

1 MR. SIRI: Do you want me to
2 cross examine the attorney?

3 MR. LEUNG: You can ask the
4 attorney questions or --

5 MR. SIRI: Because I -- the
6 witness -- I mean --

7 MR. LEUNG: Go ahead.

8 MR. SIRI: It depends on the
9 fashion. We may -- I may deflect it
10 to her.

11 MR. LEUNG: It's pretty
12 liberal. If your question is a
13 medical question directed at the
14 attorney --

15 MR. SIRI: Yeah.

16 MR. LEUNG: -- they are allowed
17 to -- to have the doctor testify and
18 then --

19 MR. SIRI: Yeah.

20 MR. LEUNG: -- which then
21 addresses the question and then you
22 have an opportunity to ask the doctor
23 questions.

24 MR. SIRI: I would love, by the
25 way, to cross examine Tom, but I am

1 sure he would like that too much.

2 MR. LEUNG: I guess if you have
3 any questions is more appropriate.

4 MR. SIRI: Mr. Merrill, excuse
5 me, that said, I would -- I have got
6 a few preliminary arguments in the
7 form of motions to dismiss, as it
8 were, and I can present those.

9 MR. LEUNG: You sure can.

10 MR. SIRI: Okay. And then I
11 have -- and then I would like to get
12 into the meat.

13 MR. LEUNG: Okay.

14 MR. SIRI: If, you know --

15 MR. LEUNG: Sure.

16 MR. SIRI: If you don't believe
17 those should be ruled on, I don't
18 know if you rule on those on the spot
19 or not, but in the same way that you
20 ruled on the application before, you
21 could rule on these applications.

22 MR. LEUNG: Yeah. None of your
23 motions to dismiss I can rule on the
24 spot, I have to make a decision
25 ruling for that.

1 So what we are going to do is,
2 assuming -- we are going to go
3 through the entire possibilities.

4 So it's factually, we are going
5 to do it, and we are going to do it
6 procedurally, so go ahead.

7 MR. SIRI: That will make it
8 long. Okay. All right. Wonderful.

9 So, in terms of, first, I won't
10 call it an application to get a
11 ruling on now, but, I guess, the
12 first ground to dismiss this summons,
13 if you look at the summons, your
14 Honor, the operative language at the
15 end provides that, you know, and I
16 believe this is, you know, this is
17 what the violation is, the Respondent
18 failed to vaccinate child, C.R., or
19 otherwise submitting proof of
20 immunity in violation of the order --
21 it uses the word "order", "order" is
22 a defined term in the summons, okay?

23 MR. LEUNG: Right.

24 MR. SIRI: And the order was
25 issued on April 9th.

1 MR. LEUNG: Yes.

2 MR. SIRI: And by operation of
3 law, expired on April 17th. Okay.
4 Because under the applicable charter
5 provision, an order of the
6 Commissioner remains effective until
7 the next meeting of the Board of
8 Health. Okay.

9 I have the -- I can just read
10 the statutory part of the provision,
11 since I have it here.

12 MR. LEUNG: Okay. If I can
13 just -- I think I understand what
14 your -- I think I understand what
15 your, you know, your argument is.
16 Your argument is that the order
17 expired. If you want to address
18 this, I will address your ultimate
19 argument.

20 MR. SIRI: Sure.

21 MR. LEUNG: It's that the
22 Section 305, as alleged by the
23 Petitioner, alleges in the
24 alternative. They are saying it
25 violated the Commissioner's order and

1 the Health Board's resolution --

2 MR. SIRI: First, your Honor,
3 respectfully, I don't see that it
4 violated the resolution.

5 MR. LEUNG: Okay.

6 MR. SIRI: Which is completely
7 different than the order.

8 MR. LEUNG: Sure.

9 MR. SIRI: Substantively, in
10 many ways.

11 MR. LEUNG: You are right, in
12 that sense. It's technically --
13 okay. You address the issue that the
14 -- they are alleging that the Board,
15 on April 17th, if you look at the
16 summons, and I am just -- I am not
17 making the argument for them, I just
18 want you to address it to save time,
19 because it's a question that I am
20 going to ask.

21 Ultimately, on April 7th -- it
22 says on the summons, on April 17th,
23 2019, the New York City Board of
24 Health unanimously approved a
25 resolution continuing the public

1 health emergency and requirements.

2 So you are saying that the

3 continuing --

4 MR. SIRI: Yeah.

5 MR. LEUNG: -- the continuing of

6 the health emergency is one thing,

7 but the actual order to comply

8 expired on April 17th?

9 MR. SIRI: Well, I am actually

10 going to say two things.

11 MR. LEUNG: Yeah.

12 MR. SIRI: The first one, your

13 Honor, it only alleged violation of

14 the order. And the order, despite --

15 even though this violation, if you

16 look, it says that it continues the

17 public health emergency. It doesn't

18 say continued by way of the order.

19 And when you actually look at

20 the order and the resolution, nothing

21 in the resolution continued the

22 order.

23 And in fact, they apply to

24 different ages, to different people

25 in different situations, you know,

1 under the charter, okay, Section --
2 Article 3.05 --

3 MR. LEUNG: Counsel --

4 MR. SIRI: No problem. No
5 problem.

6 MR. LEUNG: No, no, I am
7 listening.

8 MR. SIRI: You are more
9 talented than I am.

10 MR. LEUNG: Go ahead.

11 MR. SIRI: So I've got -- it's
12 in Article 3, Section 3.0 of the
13 charter, it says that, you know, the
14 Commissioner's order is that -- that
15 the exercise of that power -- so, to
16 quote, "Any such acts of power shall
17 be effective only until the next
18 meeting of the Board". Okay. So, by
19 operation of law, it ends at the next
20 board meeting.

21 Unless, now, the Section 3.0
22 says the Board may -- may -- continue
23 or rescind, okay, the Commissioner's
24 -- let's just call it order, okay?
25 They have that choice. They could

1 have continued or rescinded.
2 Interestingly, it doesn't say
3 modified. They could have said --
4 they could have done it but they
5 didn't. The resolution, nowhere
6 therein, says they are continuing or
7 rescinding the order.

8 Instead, they did something of
9 their own making. And they have
10 every right. They can, I guess, do
11 that.

12 But what they didn't do was
13 provide in there that they are
14 continuing the order, nor provide
15 that they are rescinding the order.

16 And the only thing that's been
17 alleged in the violation, you can see
18 it in the summons, is the violation
19 of the order. And that order, by its
20 terms, expired -- by operation, it
21 expired on the 17th of April, the
22 violation at issue here, your Honor,
23 was issued -- was for occurrence on
24 April -- April 21, which would have
25 been four days after the expiration

1 of the order, hence, there cannot be
2 -- there cannot be a violation of an
3 order on that date since it was no
4 longer in existence.

5 MR. LEUNG: Okay. I am going
6 to turn to counsel for DOH and ask
7 how you respond.

8 MR. MERRILL: I am going to
9 start with the citation of the health
10 code, which is 305, and it says it is
11 in violation of the order --
12 (indiscernible) 305.

13 They would be in violation of
14 the Commissioner's order or it can be
15 a violation of any order for the
16 basis --

17 (Indiscernible.)

18 MR. LEUNG: And you are
19 referring to the actual statute,
20 3.05?

21 MR. MERRILL: Correct, the
22 health code section.

23 MR. LEUNG: Okay.

24 MR. MERRILL: And then in terms
25 of -- how is it the Commissioner

1 exercised, pursuant to the emergency,
2 was the Board's power, which exists
3 there, in 78 -- 148 -- 142 of the --
4 code.

5 The Commissioner did that on
6 April 9th in her power to declare an
7 emergency exists, only until the
8 Board meeting. But at the Board
9 meeting, it did issue an order that
10 requires all residents of
11 Williamsburg to be vaccinated.

12 The fact that it may have --
13 the Board -- the Board, in any such
14 exercise of its authority, under the
15 administrative code and charter, the
16 difference might be in the language
17 of that order, it doesn't change the
18 fact that the order, issued on
19 April 9th -- that was on April 15th
20 -- whatever date the Board met --

21 MR. LEUNG: 17th.

22 MR. MERRILL: The 17th. --
23 required all residents to be
24 vaccinated and that this person
25 violated that order as charged in the

1 -- as required by the that Health
2 Code Section 3.05.

3 MR. SIRI: I don't -- I don't
4 dispute, at all, that Section 3.05,
5 exactly as opposing counsel stated,
6 yeah, it -- it permits issuing
7 violations for violating any order,
8 resolution, anything. It could have
9 been for having rats in your
10 restaurant, right?

11 But you are only going to be
12 charged -- you have to be noticed of
13 what you are charged and the charging
14 language here was not for violating
15 the resolution, it was for violating
16 the order. That's what it --

17 MR. LEUNG: Respond to that.

18 MR. SIRI: May I make one more
19 point, your Honor?

20 MR. LEUNG: Yeah.

21 MR. SIRI: And I think it is
22 very telling that counsel kept
23 talking about the, you know, the
24 resolution applies to residents,
25 right?

1 Well, you know, it's a great
2 point to show you the difference
3 between the order and the resolution.
4 Because in the order, to be sure,
5 counsel's correct. It did apply. It
6 did apply to a resident. It
7 specifically provides that it applies
8 to any person who lives, works, or
9 resides within these certain zip
10 codes.

11 But if you look at the
12 resolution, it didn't include
13 residents, it only included the --
14 the people who live or work --

15 MR. LEUNG: Where are you
16 looking on the resolution? This
17 little paragraph?

18 MR. SIRI: Absolutely. So in
19 the order, if you look at the first
20 ordered paragraph, okay, and the very
21 first sentence says that any person
22 who lives, works, or resides --

23 MR. LEUNG: Right.

24 MR. SIRI: It's on the second
25 page.

1 MR. LEUNG: Got you.

2 MR. SIRI: So first, second
3 page, the operative ordered language
4 of the order --

5 MR. LEUNG: I got you. I got
6 you.

7 MR. SIRI: And go to
8 resolution, and you go and you look
9 at the -- to the resolved language,
10 and you, please, look at the second
11 resolve paragraph, it says that the
12 Board hereby -- any person who lives
13 or works within the affected zones.

14 They left out people who are
15 residents, meaning, if you reside in
16 there, and you have left, you are not
17 living there, right? So if you went
18 upstate, you are good, where the
19 order did apply to people who resided
20 there. So even if you left, you
21 were, apparently, still in violation,
22 amazingly.

23 I mean, so, you know, it's a
24 great, you know, it's a great
25 highlight to how what the Board did

1 was different than what the
2 Commissioner did.

3 MR. LEUNG: How do you -- I am
4 just looking at it briefly, to the
5 second to last resolve paragraph --

6 MR. SIRI: Please.

7 MR. LEUNG: -- and resolution.

8 MR. SIRI: That's right.

9 MR. MERRILL: I am looking at
10 the third -- the fourth one -- it
11 says the Board hereby declares that
12 any person who lives and works within
13 the affected zip codes shall be
14 vaccinated.

15 MR. LEUNG: Just tell me what
16 you are reading, is it the resolution
17 --

18 MR. MERRILL: I am reading the
19 order. I am reading the order, the
20 Board of Health resolution.

21 MR. LEUNG: And which resolve?

22 MR. MERRILL: The second page
23 at the very bottom.

24 MR. LEUNG: Okay. Under
25 "resolved"?

1 MR. MERRILL: Correct.

2 MR. LEUNG: First, second,
3 third, fourth --

4 MR. MERRILL: No, second
5 resolved.

6 The Board of Health hereby
7 declares that any person who lives,
8 who works within the affected zip
9 code shall be vaccinated. So it --
10 that's residents, people who live or
11 work within.

12 The next one goes onto -- it
13 does cover people who live --

14 MR. LEUNG: He pointed that
15 out, how do you want to respond?

16 MR. SIRI: Right. I think
17 there is a distinction between
18 children and adults, right? So...

19 MR. MERRILL: Any person. I
20 mean a think a person is a person. I
21 don't --

22 MR. SIRI: Well, in the way I
23 read it isn't that it -- it goes into
24 -- it -- it's a semantical point to
25 be sure, right?

1 MR. LEUNG: Okay.

2 MR. SIRI: But the operative
3 point -- you understand the argument?

4 MR. LEUNG: I understand the
5 argument.

6 Counsel for DOH says -- is
7 pointing to the second resolve, and
8 you are pointing at the second
9 resolve, saying you interpret it one
10 way --

11 MR. SIRI: Right. But the --
12 but the obviously more important
13 point is that, you know, the alleged
14 violation, as per the order, the
15 order was not in effect on the date
16 of the issuance of the summons.

17 And it wasn't, by anything, I
18 mean I don't see any language in the
19 resolution saying the order is hereby
20 continued.

21 MR. MERRILL: To respond to
22 that, if you go into the middle of
23 the NOV, I mean especially in the
24 resolution, again, with the fact that
25 on April 17th, the Board approved the

1 resolution continuing the public
2 health emergency and the requirement
3 that all persons living or working or
4 attending schools in these affected
5 zip codes be vaccinated against
6 measles.

7 The resolution further provides
8 that any person who is not vaccinated
9 by a parent or guardian of a child
10 who is not vaccinated shall be find
11 unless they demonstrate proof of
12 immunity. I think that NOV clearly
13 puts on the notice that the
14 resolutions and the facts, that they
15 are being charged with violating the
16 resolution.

17 MR. SIRI: I did not hear
18 anywhere in there that the resolution
19 was continued -- that the order was
20 continued from what was just read.

21 I mean I --

22 MR. MERRILL: I think that's
23 Section 3.05 --

24 MR. SIRI: I don't think that
25 applies. I think if you are going to

1 charge people and require them to
2 inject something into their
3 children's body, you should be clear
4 about, you know, whether the order is
5 continued.

6 You know, this section, the
7 charter is clear. They can continue
8 it or they can rescind it. The Board
9 didn't choose to do either of those.
10 It chose to issue -- I will give you
11 a few examples, just a few quick
12 examples, that I do know, of clear
13 differences.

14 I jumped on the resident point,
15 but I will -- so, for example, in the
16 order, okay, the order applied to
17 those over six months of age. The
18 resolution included those six months
19 of age.

20 MR. LEUNG: Can you just point
21 to --

22 MR. SIRI: Absolutely.

23 So if you look at the -- if you
24 look at the order, in the -- in -- it
25 is further ordered that the parent or

1 guardian of any child older than six
2 months of age --

3 MR. LEUNG: What paragraph are
4 you referring to?

5 MR. SIRI: It's the number
6 paragraph, it's the second to last
7 paragraph of the order, "it is
8 further ordered" --

9 MR. LEUNG: Okay. I see that.

10 MR. SIRI: Older than six
11 months. And then --

12 MR. LEUNG: Any child over six
13 months of age, okay.

14 MR. SIRI: And then if you look
15 at the resolution, it says that in
16 this -- and this is in the third to
17 last resolved paragraph, I don't know
18 the technical term for that --

19 (Indiscernible.)

20 MR. SIRI: Sorry, third to last
21 resolved paragraph, it says that the
22 parent or guardian of any child six
23 months of age or older. So you have
24 a difference in terms of the age of
25 that -- that it applies to between

1 the resolution and the order. They
2 are saying that --

3 MR. LEUNG: You are saying
4 there is a month difference --

5 MR. SIRI: A month difference.

6 MR. LEUNG: Sorry, say it one
7 more time.

8 MR. SIRI: One month
9 difference. So the order did not
10 apply to six-month-olds.

11 MR. LEUNG: So when the child
12 is six months of age or older and we
13 estimate that child to be under
14 whatever how many days six months is,
15 are you saying that the statute is
16 written -- it has to -- by month
17 increments? I mean --

18 MR. SIRI: I'm just saying they
19 are different. I'm saying they are
20 different.

21 MR. LEUNG: Right.

22 MR. SIRI: I am saying that
23 what the Board did is different than
24 what the order did. I'll give you
25 some other changes.

1 MR. LEUNG: Go ahead. Okay. I
2 am going to make -- let the record
3 reflect that I understand your
4 argument regarding the six months
5 reference in the order and the six
6 months reference in the resolution.

7 MR. SIRI: Is it clear -- so
8 the order did not apply to
9 six-month-olds, meaning, they
10 couldn't issue a violation, a child
11 that was six months of age under the
12 order for not having an annual --

13 MR. LEUNG: Do you mean the
14 resolution --

15 MR. SIRI: Under the -- under
16 the order. The order of six months
17 was older than six months. The
18 resolution said six months or older.

19 So the --

20 MR. MERRILL: The resolution
21 brings in one extra day --

22 MR. SIRI: The resolution does
23 allow providing violations to those
24 who are six months of age.

25 MR. LEUNG: Okay.

1 MR. SIRI: Okay but what the
2 order does --

3 MR. LEUNG: And, Counsel, the
4 significance of that is what?

5 MR. SIRI: Well, for this
6 client, I have violations -- but for
7 this client, the significance is that
8 -- is that the Board didn't just --
9 first of all, it never says in the
10 resolution we are continuing the
11 order.

12 MR. LEUNG: Right. I
13 understand that --

14 MR. SIRI: Second -- and -- and
15 there are differences. It doesn't
16 say, okay, what you did, in the
17 order, we are continuing it. No, it
18 says, okay, we are going to have
19 different resolve language.

20 One is, we are going to apply a
21 different age group, two is, and this
22 also is critical, the order refers --
23 calls the people who are not
24 receiving the MMR the nuisance.

25 MR. LEUNG: Say that one more

1 time.

2 MR. SIRI: The order -- the
3 order characterizes the nuisance as
4 those who haven't received an MMR
5 shot.

6 MR. LEUNG: What paragraph are
7 you referring to?

8 MR. SIRI: So it's the -- okay.
9 So it's the second to last whereas
10 clause in the order.

11 MR. LEUNG: Okay.

12 MR. SIRI: I find that the
13 presence of any person in
14 Williamsburg lacking the MMR
15 vaccine...is therefore a nuisance.

16 MR. LEUNG: That's in the New
17 York City Health Administration Code
18 17-442, okay.

19 What do you want to point out
20 that's different in the order -- the
21 resolution?

22 MR. SIRI: And then the
23 resolution, if you look at the first
24 resolved paragraph, it says that the
25 outbreak poses a public nuisance.

1 So the, you know, the -- I will
2 let you find it.

3 MR. LEUNG: No, no, I found it.

4 MR. SIRI: So, you know, the
5 Board characterizes the outbreak as
6 the nuisance. The order
7 characterizes the folks who didn't
8 receive the MMR vaccine as the
9 nuisance, as just another example of
10 the difference.

11 I will give you another
12 example. The order --

13 MR. LEUNG: Counsel, I am going
14 to ask you to do two things.

15 Number one, I understand that
16 there is differences in language
17 between the order and the resolution,
18 I want you to go one step further and
19 give me a conclusion. And, therefore
20 --

21 MR. SIRI: Okay.

22 MR. LEUNG: -- give me the
23 significance of the difference in
24 language, how it supports your
25 argument.

1 MR. SIRI: Absolutely. Can I
2 just point out for the record another
3 --

4 MR. LEUNG: Sure. Yeah.

5 MR. SIRI: The order did not
6 apply to schools, preschools, or
7 child care.

8 MR. LEUNG: What are you
9 looking at here, just point to --

10 MR. SIRI: Sure. If you look
11 at the order language on the order,
12 if you look at the two order
13 paragraphs, it doesn't say anything
14 about school, preschool, child care.
15 It just said people who live, work,
16 or reside, okay?

17 MR. LEUNG: Okay.

18 MR. SIRI: Versus look at the
19 third to last resolved paragraph in
20 the resolution, it does include those
21 who are attending school, preschool,
22 or child care.

23 So you didn't have to live,
24 work, or reside in the affected zip
25 codes, okay?

1 MR. LEUNG: I understand your
2 argument.

3 MR. SIRI: Those are the few
4 other differences.

5 MR. LEUNG: Sure. No. Whatever
6 you want to put, I am not going to
7 cut you short --

8 MR. SIRI: Sure.

9 MR. LEUNG: What other things
10 do you want to point out that's a
11 difference between them?

12 MR. SIRI: Okay. And, so, the
13 order provided for criminal finds,
14 forfeiture --

15 MR. LEUNG: Which page are you
16 referring to?

17 MR. SIRI: Sure. Absolutely.
18 The last page under the warning.

19 MR. LEUNG: Right.

20 MR. SIRI: It provides for
21 criminal finds, forfeiture, and
22 imprisonment for not complying with
23 the order.

24 MR. LEUNG: What paragraph are
25 you referring to?

1 MR. SIRI: Under the warning --
2 oh, flip that page over. They are
3 saving the trees, that's good.

4 MR. LEUNG: Yes.

5 MR. SIRI: In the first
6 paragraph, under warnings --

7 MR. LEUNG: Got you.

8 MR. SIRI: The resolution does
9 not provide for forfeiture, for
10 criminal finds, or imprisonment.

11 MR. LEUNG: Okay. Well, let me
12 just say this. The warning isn't --
13 I mean I am just making an
14 observation, how do you address the
15 fact that this warning isn't the law?
16 I mean it's just pointing out what
17 the law provides and it's almost like
18 a label saying, hey, the law provides
19 that.

20 I mean the absence of this
21 warning doesn't mean that the law is
22 in effect and the presence of this
23 warning doesn't make the law in
24 effect. The law is what the law is.

25 MR. SIRI: Well, respectfully,

1 the Health Code provides discretion
2 to the Health Department to choose
3 the penalty.

4 MR. LEUNG: So you are saying
5 that the presence of this warning,
6 which gives you the warning that this
7 is a misdemeanor, that's in your --
8 in the absence of that warning in the
9 resolution is what you are pointing
10 out to? Is that what you are
11 pointing out?

12 MR. SIRI: I'll point out the
13 following words.

14 MR. LEUNG: Sure.

15 MR. SIRI: Right before that.
16 It's not just that this is the law.
17 It says that failure to comply with
18 this order is a violation and a
19 misdemeanor for which you may be
20 subject to these things.

21 MR. LEUNG: So where --

22 MR. SIRI: So it wasn't just
23 the general law.

24 MR. LEUNG: Right.

25 MR. SIRI: The point is that

1 that is what is being threatened
2 under the order --

3 MR. LEUNG: Right.

4 MR. SIRI: -- absent from the
5 resolution. Just another -- there
6 are other distinctions. I will -- I
7 can see them -- I can get to the end
8 if you want.

9 MR. LEUNG: No, you can -- you
10 can -- I just have to -- because I
11 have to write the decision, I have to
12 understand it all.

13 MR. SIRI: Yes. Sure. So that
14 is another -- is there -- so that is
15 another -- obviously, what the
16 penalty is --

17 MR. LEUNG: Can you just --

18 MR. SIRI: Yes.

19 MR. LEUNG: Can you explain to
20 me how you are pointing out
21 differences between the order and the
22 resolution?

23 MR. SIRI: Yes.

24 MR. LEUNG: To what end is that
25 supporting your motion to dismiss,

1 what is your --

2 MR. SIRI: Absolutely. What it
3 points out is this. I believe
4 counsel was saying that, well, you
5 know, the resolution talks about the
6 order itself, it continued it
7 somehow.

8 But the resolution never says
9 it continues it. And not only does
10 it not say that it continues it,
11 which is critical in continuing an
12 order, you have to say you continued
13 it or you withdrew it, they didn't do
14 either of those, right? It actually
15 has all kinds of differences.

16 The Board chose to do something
17 different, and that's fine, it chose
18 to do that. And, so, you have a
19 resolution that stands on its own.
20 You have an order that stands on its
21 own, okay?

22 This resolution --

23 MR. LEUNG: Can a resolution
24 add things and do things and also
25 continue the order, in your opinion?

1 MR. SIRI: If you look, and
2 it's not my opinion, if you look at
3 the charter provision, Section 3.01,
4 it says that the Board may continue
5 or rescind as soon as the
6 Commissioner's order -- it doesn't
7 say modify, it doesn't say amend, it
8 says continue or rescind it, and it
9 could have chose to do that --
10 Section 3.01 -- sorry, it's under the
11 Admission Code. It's under the
12 rules --

13 MR. LEUNG: It's the health
14 code.

15 MR. SIRI: Oh, it's the health
16 code. Well, they can leave here and
17 change it, if they want, I guess.

18 MR. LEUNG: You said what? You
19 have to give -- before we forget
20 everything you said, do you want to
21 address --

22 MR. MERRILL: I think Mr. Siri
23 is coming at this a little bit
24 backwards. If you look at 3.01, the
25 -- what he is saying, his position is

1 the Commissioner can act in an
2 emergency and then the Board's hands
3 are tied to do only what the
4 Commissioner has done or to rescind
5 in entirety.

6 But if you look at 3.01, what
7 that does is it gives the
8 Commissioner the authority in an
9 emergency to step up and to act and
10 use the Board's power, because of the
11 emergency, to, among other things,
12 exercise its powers to prevent,
13 mitigate, control, in cases of
14 emergency, provided that that will be
15 effective until the next Board of
16 Health meeting.

17 And the purpose is, if you look
18 at -- the chief's playing the role of
19 the Board, the Board comes in and
20 there is nothing that limits the
21 Board's authority and ability to take
22 whatever it deems to be appropriate
23 action to, you know, address that
24 emergency or that order.

25 So I agree that the orders are

1 not 100 percent amendable. There are
2 minor differences in them. But the
3 bottom line is with what was true and
4 that there was a resolution in effect
5 by the Board of Health, under its
6 power, to abate nuisances in the
7 city, directing all residents of
8 Williamsburg to be immunized. That
9 was violated and it is in the NOV.

10 I will point out one of the
11 differences here, you know, in terms
12 of the criminal language, which is
13 standard language we have in all of
14 our orders, even though we typically
15 won't enforce the penalty, the reason
16 it is not in there anymore is that we
17 are challenged, the Board's authority
18 was challenged in the Supreme Court.

19 And in the course of that
20 argument, what people were claiming,
21 we are going to be arresting people,
22 no, we never intended -- we were
23 going to enforce that civilly. And
24 that was going on at the same time
25 while we were going on between, you

1 know, the order and the Board's
2 action.

3 And, so, the Board's action
4 doesn't reference criminal stuff --
5 reference sanctions because we
6 acknowledge when the authority of the
7 Board was being challenged and the
8 authority was being held by the
9 Supreme Court, that we were going to
10 be enforcing that document.

11 The bottom line is I don't
12 agree with Mr. Siri, that the order
13 -- that there is anything that
14 requires the Board's resolution/order
15 to be identical in form to the
16 Commissioner's because it has the
17 authority, and she was using its
18 authority, to take the actions it
19 deems appropriate. And it did that
20 when it issued its resolution
21 continuing that people be vaccinated
22 and that's what this person violated.

23 MR. SIRI: Your Honor, I think,
24 maybe, we are agreeing then that the
25 order was null on the 17th and all

1 that remains --

2 MR. MERRILL: Was an order of
3 the Board.

4 MR. SIRI: -- was a resolution
5 of the Board --

6 MR. MERRILL: Which is an order
7 which directs all people.

8 MR. SIRI: But that's not
9 what's alleged in this. They are
10 alleging a violation of the order,
11 which is only the Commissioner's
12 order, not the resolution.

13 MR. MERRILL: The NOV clearly
14 says that you are required to be
15 vaccinated by the Board of Health
16 resolution. 3.05 references
17 resolution, the Board action, she
18 violated the Board action.

19 MR. SIRI: Yeah but the
20 violation -- the summons clearly
21 states says Respondent failed to
22 vaccinate child or submit acceptable
23 proof in violation of the, capital
24 "O", order, and order is defined as
25 the Commissioner's order.

1 And that was a nullity at the
2 time that this summons was issued,
3 irrespective of this, you know, the
4 nuisances are going to be modified.
5 The point is that order is gone.

6 MR. LEUNG: Do you want to
7 respond to that?

8 MR. MERRILL: Again, I think
9 there are semantics here. The
10 resolution is an order.

11 So if you read this NOV, it
12 clearly puts you on notice that there
13 is a requirement that you be
14 vaccinated that you are violating.

15 So I mean, you know, we can,
16 again, you know, the fact of the
17 matter is the resolution -- the use
18 of resolution -- the use of order,
19 there was a requirement that you be
20 vaccinated that's in this NOV that
21 wasn't complied with.

22 And 3.05 makes it clear that
23 the Board directs you to take action,
24 and you violate that, that is a
25 violation of 3.05.

1 MR. SIRI: I think the
2 violation alleges clearly what they
3 are alleging was violated and it only
4 says order.

5 MR. LEUNG: Before -- I think I
6 have enough to make a decision -- I
7 just want to clarify, factually, Mr.
8 Siri, there was an argument you made
9 regarding the child being either --
10 the order -- the difference between
11 the order and the resolution, one
12 being six months or older, and the
13 other one being --

14 MR. SIRI: I think that's a
15 secondary point.

16 MR. LEUNG: No, but I need to
17 establish for the record.

18 MR. SIRI: Yeah.

19 MR. LEUNG: Do you believe that
20 your client, again, your client, I
21 don't know if it's the parent or the
22 child, but do you believe that the
23 child at issue here falls factually
24 within that -- in other words, do you
25 believe that at the time of the

1 summons, that the child was exactly
2 at six-months-old or six months plus
3 one day?

4 MR. SIRI: No, I am not making
5 that argument based upon -- this
6 client was not six months of age.

7 MR. LEUNG: Or six months and
8 one day, correct?

9 MR. SIRI: No, that is not the
10 issue. The issue is that they are
11 charging that my client violated an
12 order on the 23rd -- on the 21st of
13 April, but that order was a nullity
14 by the April 17th. That's the issue.
15 The rest of it is window dressing,
16 everything else around it.

17 MR. LEUNG: So I have enough to
18 make a decision. I am just going to
19 summarize, and I will allow both
20 sides to make arguments, the issue in
21 this case appears to be whether or
22 not the -- first off, the
23 Petitioner's 1, which is the order of
24 the Health Department Commissioner
25 issued on April 9th, 2019, which

1 everyone agrees remained in effect
2 until the next scheduled Board of
3 Health meeting, which was on
4 April 17th. Petitioner's 2 is the
5 Board of Health resolution dated
6 April 17th.

7 There is a dispute as to
8 whether the language of the Board of
9 Health resolution, number one,
10 continued the order issued by the
11 health commissioner.

12 The record should reflect that
13 counsel, Mr. Siri, has made an
14 argument that there is no explicit
15 language in the resolution, P2, which
16 directly states, in sum and
17 substance, that the Commissioner's
18 order is hereby continued. There is
19 nothing expressed in that and that is
20 agreed that -- from the Health
21 Department -- that there is nothing
22 expressed.

23 The issue as to whether or not
24 continued is a factual issue,
25 irrespective of whether or not the

1 Department of Health conceives that,
2 I understand your argument.

3 The second issue is whether or
4 not the resolution, on its own,
5 Petitioner's 2, was something that
6 was alleged in the summons, putting
7 Respondent on notice that he needed
8 to comply with P2, the resolution.

9 And I understand both sides,
10 that's why we are here, and I will
11 allow both sides to make an argument.

12 Mr. Siri, is there anything
13 that you want to add?

14 MR. SIRI: Yeah, just to say
15 that even though it references the
16 resolution -- in fact, by referencing
17 resolution, it defines resolution in
18 this violation. It specifically
19 defines the word, if you look at
20 violation.

21 MR. LEUNG: Just for the
22 record, what are you reading, what
23 are you looking at?

24 MR. SIRI: Right. If you are
25 looking at the Summons --

1 MR. LEUNG: We are looking at
2 the summons. Go ahead.

3 MR. SIRI: You can see it
4 starts by referencing the
5 Commissioner's and it defines the
6 word "order"; do you see that?

7 MR. LEUNG: Just tell us --
8 state the language you are reading.

9 MR. SIRI: Absolutely. It says
10 -- so the violation description
11 begins: In response to the active
12 measles outbreak in certain parts of
13 Brooklyn and New York, City
14 Commissioner of Health declared a
15 public health emergency on April 9th,
16 2019 and published a commissioner's
17 order.

18 MR. LEUNG: Right.

19 MR. SIRI: Defined as order,
20 brackets, parenthesis, order, closed
21 parenthesis, closed bracket.

22 MR. LEUNG: Right.

23 MR. SIRI: So order means the
24 Commissioner's order. That expired
25 by operation of law on April 17th. I

1 believe there is no dispute about
2 that.

3 MR. LEUNG: Can I stop you
4 there?

5 MR. SIRI: Yeah.

6 MR. LEUNG: And I understand
7 your argument.

8 MR. SIRI: Yeah.

9 MR. LEUNG: Can you address
10 this argument? Because ultimately, I
11 have to write a decision, and this is
12 something that I want both sides to
13 address.

14 The following sentence on the
15 summons, which is the second full
16 sentence, on April 17th, 2019, a New
17 York City Board of Health unanimously
18 approved the resolution continuing
19 the public health emergency and
20 requirement that all persons living,
21 working, or attending school in these
22 affected zip codes be vaccinated
23 against measles --

24 MR. MERRILL: I would like to
25 make reference, your Honor, to that

1 one too, as well, which is the
2 resolution further provides that any
3 person who is not vaccinated or the
4 parent or guardian of a child shall
5 be fined unless they demonstrate
6 proof of immunity or that
7 immunization is not appropriate or --

8 MR. LEUNG: I guess the
9 question that I have is --

10 MR. SIRI: I would like to
11 continue reading it, your Honor,
12 because it goes on it and it says --
13 and I agree --

14 MR. LEUNG: No, no, I
15 understand you agree. Go ahead.

16 MR. SIRI: Yeah. And then it
17 goes on and it says in review of the
18 records. And then it ends by saying
19 that Respondents failed to vaccinate
20 -- in violation of the order. It is
21 alleging a violation of the order.
22 That is all that this violation --

23 MR. LEUNG: Mr. Siri, I
24 understand your argument that a
25 portion of the allegation on the

1 summons refers only to the order.

2 What I would like to address in my
3 question is the following sentence,
4 on April 17th, 2019, the New York
5 City Board of Health unanimously
6 approved a resolution --

7 MR. SIRI: That's right.

8 MR. LEUNG: And resolution is
9 in the paragraph --

10 MR. SIRI: That's right.

11 MR. LEUNG: Continuing the
12 public health emergency and
13 requirement that all persons living,
14 working, or attending school be
15 vaccinated against measles.

16 The resolution further provides
17 that any person who is not vaccinated
18 or the parent and/or guardian of the
19 child who is not vaccinated shall be
20 fined unless they demonstrate proof
21 of immunity or that immunization is
22 not medically appropriate.

23 How do those two sentences not
24 put your client on notice that they
25 were to comply with the resolution,

1 irrespective of your argument that
2 the final sentence only refers to the
3 order?

4 MR. SIRI: Because, your Honor,
5 words have meaning. And in the
6 violation description, it has to tell
7 you what you are in violation of.

8 The fact that it has -- I think
9 the fact that it even defined the
10 word resolution further supports why
11 they chose, your Honor, to say, at
12 the end, you are in violation of the
13 order, I don't know. That's their
14 choice. But that's what they chose
15 to say that my client was in
16 violation of.

17 It did not say my client was in
18 violation of the resolution in this
19 violation description. I think if
20 you want to -- we are not talking
21 here about giving somebody a little,
22 you know, you are talking here about
23 requiring an injection of a product
24 into somebody's body.

25 I think you need to give some

1 very clear and explicit notice of
2 what you are alleging they are
3 violating. I think if you don't
4 reference the right order, code,
5 section, that's on them.

6 That's the least, your Honor, a
7 minimum safeguard to due process -- a
8 minimal safeguard to due process
9 required you to make clear what is it
10 is you are violating.

11 They wrote you violated the
12 order, they chose to do that, you
13 know, that's it. If they wanted to
14 say you violated a resolution, they
15 could have done that.

16 It shouldn't have to be -- my
17 client is not a lawyer, who is not an
18 attorney, who doesn't speak English
19 that well, to try to figure out
20 precisely what it is, you know, they
21 are being claimed they are in
22 violation of. They should be able to
23 read it and say, okay, it says I am
24 violating the order, okay? Period.

25 MR. LEUNG: Okay. I don't know

1 if you answered my question but I
2 think you did.

3 You are saying that the final
4 sentence, because it contains the
5 alleged violation of the order,
6 controls because there is no sub --
7 there is no equivalent allegation.

8 In other words, there is no
9 Respondent failed to vaccinate child
10 or otherwise submit acceptable
11 immunity in violation of the order or
12 resolution, which is what you are
13 saying is required, if they are going
14 to allege that he violated the
15 resolution; is that a correct
16 summation?

17 MR. SIRI: Right. It should
18 say -- the charge should say, you
19 know, if you look at charging
20 documents, it says in charging
21 documents in criminal court, this is
22 what you violated. It tells you what
23 you violated.

24 It doesn't say in here my
25 client violated the order. It

1 doesn't say in here that they
2 violated the resolution. That's not
3 what's alleged.

4 MR. LEUNG: Anything else from
5 the other side?

6 MR. MERRILL: Your Honor, the
7 NOV is only -- to the extent that it
8 puts you on notice of the resolution,
9 it does that, and it cites 3.05, and
10 that's the doctor's --

11 MR. LEUNG: I have enough to
12 make a decision. Is there anything
13 else anyone wants to put on the
14 record before I close the hearing?

15 MR. SIRI: On just that
16 argument -- I have lots of other
17 arguments, that's just the first.

18 MR. LEUNG: You have other
19 things?

20 MR. SIRI: Oh, yeah, that's
21 just the first. That's just the
22 first argument. I have lots of
23 arguments. Oh, no.

24 MR. LEUNG: Let's move on --

25 MR. SIRI: You said you are

1 going to rule on that argument?

2 MR. LEUNG: No, I don't rule on
3 anything. I take things under the
4 advisement and I make decisions in
5 30 days.

6 The only thing that I ruled
7 here today was your request to have
8 the --

9 MR. SIRI: The hearing officer
10 --

11 MR. LEUNG: The issuing
12 officer --

13 MR. SIRI: I apologize, the
14 issuing officer.

15 MR. LEUNG: Because of that
16 hurdle, obviously, by rule, that you
17 are entitled to it, but I am going to
18 adjourn the hearing.

19 So whether or not we have the
20 hearing is determining on making that
21 decision. That's why --

22 But everything else, the motion
23 to dismiss, your arguments, I am
24 going to take under advertisement.

25 Since you have many other

1 decisions and we have many other
2 cases, I am going to ask you to move
3 on to your next argument.

4 MR. SIRI: Yes. Absolutely.
5 Okay.

6 So, the second ground, your
7 Honor, that we move on to that this
8 summons was not properly issued is
9 that pursuant to the New York
10 Administrative Code Section 17-148C,
11 okay, it provides that the Board's
12 resolution must be published for
13 three days before the public is
14 deemed to be on notice of the
15 requirements of the resolution.

16 MR. LEUNG: Okay.

17 MR. SIRI: Okay. If, your
18 Honor, would like, I can read into
19 the record the provision.

20 MR. LEUNG: I have it. You
21 don't need to read it.

22 MR. SIRI: Wonderful. I'll
23 keep going.

24 MR. LEUNG: So you are saying
25 it failed to do that?

1 MR. SIRI: Right. And I would
2 like to put into evidence -- do you
3 have the publications notice?

4 I so have the -- so I am going
5 to be handing, your Honor, a copy of
6 the city register, Notice of
7 Publication of the Resolution.

8 MR. LEUNG: I am going to mark
9 this as Respondent's -- did you put
10 anything else into evidence at all?

11 MR. SIRI: Not yet.

12 MR. LEUNG: Let the record
13 reflect that Respondent's 1 is a
14 printout of the New York City Record
15 of Online Reports for the Board of
16 Health Measles Resolutions, dated
17 4/17/2019, publication date lists
18 here as 4/22 to 4/24/2019.

19 Any objection for this coming
20 into evidence? The Department of
21 Health does not object. Respondent's
22 1 has been submitted into evidence.

23 (Whereupon, a document was marked
24 as Respondent's Exhibit 1, for
25 identification, as of this date.)

1 MR. LEUNG: What would you like
2 to comment upon this R1?

3 MR. SIRI: Sure. So the
4 publication, the three days, ended on
5 April 24th. But, yet, the violation
6 was issued on April 21st, that's the
7 date and time of occurrence written
8 on the summons, your Honor, which
9 means it was issued, not even during
10 the three days, which, itself,
11 wouldn't have been valid.

12 It was issued even before the
13 three days of notice that was
14 required for publishing the
15 resolution.

16 MR. LEUNG: Counsel for DOH?

17 MR. MERRILL: I just want --
18 (Indiscernible.)

19 MR. MERRILL: I think you can't
20 have it -- so, you know, if he is
21 going to say that the Board of Health
22 resolution was in effect, then the
23 order is still in effect. It can't
24 be -- it can't be that there is this
25 gap. So either one has to be -- it

1 can't be one or the other.

2 MR. SIRI: Two quick things.

3 Obviously, this is an argument in the
4 alternative, correct, in that -- I
5 just want to make it very clear for
6 the record that our position is the
7 resolution is not alleged to be
8 violated in this order -- excuse me
9 -- in this summons.

10 So I am arguing on the term
11 that that to the extent that you
12 found the resolution to actually be
13 in effect and that the resolution --
14 excuse me -- was alleged to have been
15 violated in the summons, despite it
16 not saying that in the summons.

17 It was not that effective --
18 that it was improper to have issued
19 this violation on the date of
20 issuance.

21 MR. LEUNG: Are you going to
22 respond --

23 MR. SIRI: And, now, to
24 directly to respond to Mr. Merrill's
25 point, the Board is free to pass the

1 resolution when it did, but that
2 doesn't change the notice
3 requirements, as we now --

4 MR. LEUNG: I understand what
5 you are saying, that the issue was on
6 4/21 and that the notice, provided by
7 this publication, was first published
8 for three days, beginning on April
9 22nd and ending on April 24th, and
10 that any summons should have been
11 issued on April 26th or 27th. The
12 fact that it was issued before it was
13 even published is insufficient notice
14 in terms of how it pertains to the
15 resolution. I understand your
16 argument and I understand your
17 position.

18 MR. MERRILL: It would be that
19 the order's date of effectiveness --
20 and when the resolution becomes
21 effective -- because the risk is
22 required and is put into effect and
23 you can't have it both ways --

24 MR. SIRI: Mr. Merrill may not
25 like the policy result of the way the

1 law works but that's what the law
2 provides. It says any -- the Board
3 power will be effective only until
4 the next meeting of the Board. It
5 was done at the Board meeting. It
6 was over.

7 The fact that there is a gap
8 between the Board meeting, right, and
9 when the notice is done -- and then
10 it issues summonses again --

11 MR. LEUNG: Can I ask a
12 relevant question?

13 MR. SIRI: Yes.

14 MR. LEUNG: Because that's what
15 I am going to look at at the hearing
16 --

17 MR. SIRI: Yes.

18 MR. LEUNG: The resolution was
19 valid, in effect, there wasn't
20 notice -- I'm sorry.

21 How do you deal with the issue
22 of -- the possible issue that
23 Petitioner might raise that the
24 Board, on the 19th, acted to continue
25 the Commissioner's April 9th order.

1 And although -- and on
2 April 21st, when your client was
3 served with the summons, the order --
4 I'm not saying -- I' m just saying
5 the order was in effect --

6 MR. SIRI: There was no
7 evidence. I assume counsel is, you
8 know, he is an attorney speaking,
9 there is no evidence on record, that
10 I'm aware of, here today so far that
11 shows that the resolution continued
12 the order, right?

13 Is it -- the only thing that
14 they pointed to is the resolution
15 language itself; is that correct?

16 MR. LEUNG: The resolution, the
17 summons, and the original order, so
18 all of the evidence that we have.

19 MR. SIRI: Right --

20 MR. LEUNG: And then --

21 MR. SIRI: Right. So,
22 nothing -- right. I would love to
23 see the language. I have read it a
24 few times. I don't see anything in
25 there that says the order of the

1 Commissioner hereby continues. There
2 is nothing in the notice.

3 So if -- what you are asking me
4 is but if you found it was continued,
5 right?

6 MR. LEUNG: Right.

7 MR. SIRI: Could a violation
8 still be issued under the order.

9 And my answer to that is no.
10 And here is why. I would say because
11 what takes the place of the order is
12 the resolution, and that's just the
13 way 3.01 is structured. It's just
14 the way, you know, laws are to be
15 enforced the way they are written.

16 And it says that any such
17 exercise of authority shall be
18 effective only until next meeting of
19 the Board.

20 So at the next meeting of the
21 Board, that Commissioner's order
22 became a legal nullity, which took
23 its place as the resolution.

24 MR. LEUNG: I don't want to --
25 I have done other cases and there are

1 situations where if the Board
2 continues the Commissioner's order or
3 finds that it's continued, that we
4 then have two live entities at that
5 point. And that's why I am asking
6 the question.

7 MR. SIRI: Yes.

8 MR. LEUNG: The live entity
9 being the Commissioner's order, and
10 then the Board's resolution. So you
11 have two live entities at that point.

12 The question that I have is
13 assuming that I find that service was
14 improper as to the resolution, I
15 would like, on the record, for you to
16 address the other possibility --

17 MR. SIRI: Yes.

18 MR. LEUNG: -- which is that the
19 resolution extended the order. And
20 although the resolution may not be
21 valid, because service was not
22 effected in a timely manner, as per
23 your argument, how do you address the
24 issue that the order could still be
25 alive at that point, by the Board's

1 action?

2 MR. SIRI: To the extent that
3 the order is, as you say, alive, by
4 operation of the resolution, it's
5 really the resolution that's alive
6 and the order becomes an exhibit to
7 it, essentially.

8 The order, itself, by operation
9 of law, is gone. It says any such
10 exercise of authority -- shall be
11 effective only until the next meeting
12 of the board. So that Commissioner's
13 order is a legal nullity.

14 That the resolution chose to
15 revise it, okay, the resolution chose
16 to do that, but it's the resolution
17 that's alive, and it's the resolution
18 that then requires notice.

19 What has happened in both
20 proceedings before, as you know, is
21 not binding, you know?

22 MR. LEUNG: I understand.

23 MR. SIRI: And the fact that,
24 you know, that folks have done things
25 certain ways can't change what the

1 law provides.

2 MR. LEUNG: And again, the
3 reason why I am saying this is that
4 when everyone leaves the room and I
5 have to write it, these are the
6 issues that I have to address.

7 How do you address the whereas
8 from -- the second from the third
9 from the bottom on Petitioner's 2,
10 the resolution?

11 MR. SIRI: Whereas second from
12 the bottom?

13 MR. LEUNG: Yeah. Third from
14 the bottom.

15 MR. SIRI: Third from the
16 bottom.

17 MR. LEUNG: Do you see that?

18 MR. SIRI: Yeah.

19 MR. LEUNG: Whereas pursuant --

20 MR. SIRI: I think that whereas
21 pursuant, that's actually supports
22 the point that I am making.

23 Whereas pursuant to Health Code
24 Section 3.01, the order issued by the
25 Commissioner is only in effect until

1 the Board of Health convenes and
2 either continues or rescinds the
3 Commissioner's exercise of authority.

4 Even though the Board made
5 clear, understood, what happens to
6 the order. It either needs to be
7 continued or rescinded, right?

8 MR. LEUNG: Right.

9 MR. SIRI: And it still doesn't
10 say in here --

11 MR. LEUNG: So what do you say
12 happened? What did the resolution do
13 to the order, in your opinion?

14 MR. SIRI: In my opinion, what
15 the resolution does is it doesn't
16 rescind it and it doesn't continue
17 it.

18 But for purposes of this
19 argument that I am making about
20 notice, I actually don't think that
21 that matters, does it?

22 MR. LEUNG: Well, the notice
23 matters to the resolution. I am
24 talking about the order.

25 So my question to you is: Your

1 position is that the resolution
2 doesn't address continuing or --

3 MR. SIRI: It doesn't address
4 continuing or rescinding, right,
5 that's right. But -- it doesn't, but
6 even if it did, it would be basically
7 revising the Commissioner's order as
8 through the resolution --

9 MR. LEUNG: We can talk a lot.
10 I am going to give the Department of
11 Health an opportunity.

12 Do you want to address some
13 important issues that I have been
14 asking?

15 MR. MERRILL: Yeah, I think you
16 have to go back and remember this was
17 an emergency that the Commissioner,
18 you know, acted appropriately.

19 The Board did continue the
20 require that people be vaccinated.
21 Now, there was exchange, yes or no,
22 whatever, but I think it cannot be,
23 you know, again, this is a remedial
24 action, too. The reason that
25 requirement has to still be in

1 effect. It had to be effective until

2 --

3 MR. LEUNG: What is your
4 position, Counsel, for DOH, regarding
5 what the Board did in its resolution
6 vis-à-vis the Commissioner's order;
7 did it rescind it, did it continue
8 it, or did it not address it in any
9 way?

10 MR. MERRILL: It doesn't -- it
11 doesn't -- it continued the basic
12 requirement, that people be immunized
13 until -- until this becomes
14 effective.

15 But I would argue that the
16 effective date of that is clearly --
17 it has to be the date that it is
18 served. And that until then, it
19 overcharged the NOV. There was a
20 requirement, under both, that people
21 be immunized.

22 And this woman was not
23 immunized, this child was not
24 immunized, and the child continues
25 not to be immunized, and that's a

1 violation of the order.

2 MR. SIRI: Objection, but
3 obviously --

4 MR. MERRILL: We can save a lot
5 of time --

6 MR. SIRI: Go ahead.

7 MR. LEUNG: Counsel, what is
8 your position, Mr. Merrill, as to
9 whether or not on April 21st, when
10 the summons was issued, as to whether
11 or not the Commissioner was ordered
12 -- Pl was or was not in effect?

13 MR. MERRILL: I -- I -- I -- I
14 think that the -- I think that the --
15 at that time, the resolution was in
16 effect, that the resolution -- it
17 says that it took effect immediately,
18 if you look at the last sentence.

19 And I would, again, I would --
20 so if you are going to say that the
21 service was short because it was
22 before the third publication, then I
23 think it's a service issue.

24 But I do believe, looking at
25 the terms of the resolution, it does

1 say effective immediately.

2 MR. LEUNG: All right. Is
3 there anything -- do you have any
4 other arguments? Because you said
5 you have a whole bunch.

6 MR. SIRI: Yeah. Oh, yes.

7 MR. LEUNG: Go ahead.

8 MR. SIRI: Third, your Honor,
9 may I -- may I just put on the record
10 constitutional arguments? I want to
11 say them to preserve them for appeal,
12 as I understand you can't rule on
13 them.

14 MR. LEUNG: Yes. You can put
15 anything you want on the record.

16 MR. SIRI: And I -- to be
17 efficient, I will just -- I will not
18 argue them, I will simply state what
19 violations, I believe, are occurred.

20 And, so, you know, I understand
21 the tribunal -- you can't deal with
22 constitutional with issues, but I
23 want to preserve for the record, that
24 holding Respondents in violation for
25 simply existing in their homes in the

1 state that God created them, issuing
2 them a violation for not injecting a
3 product into their children against
4 their informed decision violates the
5 constitutional rights to informed
6 consent under the New York State
7 Constitution and US Constitution,
8 parental choice, under the New York
9 State Constitution and US
10 Constitution, bodily integrity, under
11 the New York State and US
12 Constitution, free exercise of
13 religion under the New York State and
14 US Constitution, substantive due
15 process to life and liberty, under
16 the New York State and US
17 Constitution, procedural due process
18 under the New York State and United
19 States Constitution, the 9th
20 Amendment right, under the United
21 States Constitution, and the cruel
22 and unusual punishment, under the New
23 York State and United States
24 Constitution.

25 And I will also add that the,

1 you know, the Commissioner's order
2 and resolution be --

3 (Indiscernible.)

4 MR. SIRI: And these summons
5 are also in excess of jurisdiction.
6 We believe error of law, arbitrary
7 and capricious, an abuse of
8 discretion, an abuse of discretion as
9 to the measure and mode of the
10 penalty.

11 And I would just like to
12 preserve those for the record, your
13 Honor.

14 I would also ask that in order
15 for me to properly address most of
16 those arguments, I would need to
17 conduct discovery.

18 And because of that, I am going
19 to make an application to depose the
20 Commissioner of the New York City
21 Department of Health, who issued the
22 resolution, as well as the -- to the
23 extent that, you know, if, your
24 Honor, found that the resolution was
25 effective here, I would also seek to

1 depose the representative of the
2 Board of Health.

3 MR. LEUNG: We have
4 representatives from the Board of
5 Health here, which --

6 MR. SIRI: The actual -- the
7 head of the Board of Health. I would
8 seek to have both of those
9 individuals.

10 MR. LEUNG: The Commissioner of
11 the Department of Health?

12 MR. SIRI: Is that the person
13 who is in charge of the Department of
14 Health.

15 MR. LEUNG: I have to check.

16 MR. SIRI: Thank you very much.
17 Then I would just seek to depose the
18 Commissioner of the Department of
19 Health.

20 MR. LEUNG: Can you just state
21 the basis for your discovery request?

22 MR. SIRI: Sure, your Honor.
23 The basis of the application is that
24 in order to make fulsome record as to
25 the violations of the New York State

1 Constitution and the US Constitution,
2 and as to various other provisions of
3 law, including C.P.L.R. -- it's
4 Article 78 of the C.P.L.R., and
5 having a fulsome record as to the
6 factual basis upon which the
7 Commissioner decided every single
8 sentence in the resolution and the
9 order is necessary.

10 I could -- I don't want to
11 belabor it, but there are lots of
12 representation in the order that, for
13 example, that measles -- with regard
14 to the measles, with regard to the
15 MMR, with regard to the safety and
16 efficacy of that product, as well as
17 with regard to the concerns regarding
18 the measles virus. And those
19 underpin the ultimate order in here.
20 And I think that the Commissioner
21 should have to answer to, you know,
22 be able to be put to the proof of her
23 claims in this order in order to
24 actually address those constitutional
25 and other grounds, which I understand

1 you can't adjudicate at this level.

2 I would also --

3 MR. LEUNG: Before that, can I
4 put on the record that we have the
5 physician here, who is a
6 representative of the Department of
7 Health, who can address those
8 underpinning questions that you have.

9 So, again, I am going to ask
10 you: What is it about the
11 Commissioner, herself, that you would
12 like to ask that cannot be answered
13 by the physician here regarding those
14 specific questions that you just
15 addressed?

16 MR. SIRI: Well, the
17 Commissioner issued the order, your
18 Honor.

19 MR. LEUNG: Well, I understand
20 that, but we have representatives of
21 the Commissioner here, who are
22 standing in for her, in terms of
23 representing them here.

24 MR. SIRI: And they are
25 speaking on her behalf?

1 MR. LEUNG: They are
2 representatives of the department,
3 just like district attorneys are
4 represented by assistant district
5 attorneys, general counsel is here
6 for them.

7 MR. SIRI: Right. So, as you
8 know, when you bring those cases, you
9 bring them against the actual
10 Commissioner, in their capacity,
11 obviously, as the Commissioner of the
12 Department, but again, it's the
13 Commissioner, themselves.

14 And, so, I am asking: Are they
15 speaking on behalf of the
16 Commissioner here today?

17 MR. LEUNG: You can ask him the
18 question. How do you want to address
19 this?

20 MR. MERRILL: I am having a
21 hard time understanding how -- I
22 think this is just harassment. I am
23 having a hard time --

24 MR. SIRI: I object to that.

25 MR. MERRILL: Hear me out.

1 MR. SIRI: It's okay.

2 MR. MERRILL: I am having a
3 hard time understanding how a
4 deposition relevant.

5 If you believe this is
6 unconstitutional -- which, by the
7 way, the Court has to agree to have a
8 deposition -- then, okay, you should
9 be able to articulate how
10 unconstitutional regardless of
11 deposing the Commissioner on what she
12 believes and science believes on
13 measles and the efficacy of the virus
14 -- of the MMR.

15 I should point out there was
16 litigation challenging the order, it
17 was upheld, so the constitutional
18 arguments were rejected.

19 In terms of the free exercise,
20 that was rejected in Prince versus
21 the City of New York. And it was,
22 again, more recently, it was rejected
23 in the unsuccessful challenge to the
24 New York State, elimination of the
25 religious exemption to vaccine.

1 So, again, you can put on
2 record that you believe all of these
3 things are unconstitutional, you can
4 -- not everyone is going to agree
5 with you, and a lot of courts haven't
6 -- but to come out and say, well, I
7 need to depose the -- and, you know,
8 ask a whole bunch of questions on the
9 medicine and why you believe measles
10 is bad and why you believe the MMR is
11 safe, I don't think -- I am having a
12 really hard time understanding how it
13 goes to those -- arguments.

14 MR. SIRI: So the only -- the
15 first instance I heard was on the
16 free exercise, not all of the other
17 grounds that I raised, just one --

18 MR. LEUNG: I --

19 MR. SIRI: And second, I am not
20 here in response to your question,
21 your Honor, on whether or not they
22 are speaking on behalf of the
23 Commissioner who actually issued the
24 order.

25 MR. LEUNG: Okay. I think

1 that's a hyper -- a technical
2 question. They are a representative
3 of the agency, which the Commissioner
4 is the head of.

5 So you are saying do they
6 directly represent and speak for the
7 Commissioner. I mean that's -- I
8 don't know -- I don't know if you
9 want to ask --

10 MR. MERRILL: So, again, I'm
11 not sure, I am taking a poke here, I
12 don't know what he wants to ask.

13 If he wants to ask our position
14 on measles and vaccines, Dr. Rosen
15 will speak to the, you know, the
16 agency --

17 MR. LEUNG: Do you know based
18 on your -- so, Counsel, based upon
19 your record, you may have more basis
20 for your reason for deposing the
21 Commissioner. I am going to deny you
22 because I believe that this doctor
23 here can answer those questions.

24 I am going to give you the full
25 opportunity to start. If you want to

1 ask the doctor questions, please do.

2 MR. SIRI: I will get to those.

3 I have just a few more quick,

4 procedural things.

5 Is it a little warm for anybody

6 here?

7 MR. LEUNG: It is. You can

8 open the door.

9 MR. SIRI: Yeah?

10 MR. LEUNG: That's the only way

11 we can get circulation in this

12 defective room, so I apologize.

13 MR. SIRI: No problem. I

14 usually like it warm. I can -- I

15 never want to make anybody sweat.

16 MR. LEUNG: Okay. Go ahead,

17 Counsel.

18 EXAMINATION BY

19 MR. AARON SIRI, ESQ.:

20 Q. I'm sorry, was it Dr. --

21 A. Rosen.

22 Q. Good morning. I am going to ask you

23 a few questions, Dr. Rosen. If you don't

24 understand any of the questions at any time,

25 please let me know, okay?

1 A. Yes.

2 MR. SIRI: And the witness was
3 sworn in?

4 MR. LEUNG: Yes, she was.

5 Q. And you understand that you are
6 testifying under the penalty of perjury,
7 correct?

8 A. Correct.

9 Q. In order to streamline some of my
10 questions, I am going to give you a list of
11 acronyms, and if you can tell me what they
12 mean, this way we have defined terms as we go
13 through some questioning relating to the
14 order.

15 HHS, what does that stand for, do
16 you know?

17 A. Oh, man, Health and Human Services.

18 Q. Yes, I believe it's the Department
19 of Health and Human Services.

20 And CDC?

21 A. Centers for Disease Control.

22 Q. And Prevention, correct?

23 Have you ever worked for the CDC or
24 have been involved with the CDC?

25 A. I have.

1 Q. When did you work for the CDC?

2 A. From 2007 through 2009.

3 Q. And what did you do there?

4 A. I served as an epidemic and
5 intelligence service officer.

6 Q. And you are aware that HHS is the
7 department under which the CDC -- is an
8 agency under the department of HHS, correct?

9 A. Correct.

10 Q. And what does the FDA stand for?

11 A. Food and Drug Administration.

12 Q. And ASIP?

13 A. Advisory Committee on Immunization
14 Practices.

15 Q. And that is a committee within the
16 CDC, correct?

17 A. Correct.

18 Q. And they are the ones who,
19 essentially, are the -- is the board that
20 decides the CDC's vaccination schedule that
21 most physicians in the country follow,
22 correct?

23 A. They make the national
24 recommendations for the routine immunization
25 program.

1 Q. So when you pull up the CDC
2 immunization schedule, that's the schedule
3 that ASIP has voted upon, essentially?

4 A. Well, it's the ACIP recommendation.

5 Q. Yep. And the IOM?

6 A. That's the Institute of Medicine.

7 Q. And that's part of the National
8 Academy of Sciences?

9 A. Correct.

10 Q. And that is not part of HHS, unlike
11 the CDC and FDA, correct?

12 A. Correct.

13 Q. They are an independent body?

14 A. Correct.

15 Q. They are hired to conduct science --
16 scientific reviews, right?

17 A. I can't speak to the process for
18 hiring.

19 Q. Is the CDC -- fair enough. Have you
20 worked for any other federal health agencies
21 other than the CDC?

22 A. No. Well, I was with the
23 Commissioned Corps --

24 Q. With the what?

25 A. I was an employee of the

1 Commissioned Corps when I was based at the
2 CDC; it's the US Public Health Service.

3 Q. Great. So you got to wear the
4 regalia?

5 A. I did.

6 Q. Are you familiar with the National
7 Childhood Vaccination Act of 1986?

8 A. I am not very familiar.

9 Q. But are you at least aware that it
10 is the act that gave immunity to liability to
11 pharmaceutical companies for injuries caused
12 by their vaccine products?

13 A. I don't know the details.

14 Q. I am asking for your -- what your
15 knowledge is. Are you aware of whether or
16 not pharmaceutical companies can be sued for
17 injuries caused by their vaccine products?

18 A. I am not aware.

19 Q. You don't know. Okay. So what do
20 you know about the National Childhood
21 Vaccination Act of 1986?

22 A. I -- that's -- I don't know
23 anything, really, about that act.

24 Q. Nothing at all. So you are not
25 aware that the manufacturer of the MMR

1 vaccine, Merck, cannot be sued for injuries
2 caused by their MMR vaccine?

3 A. I am not familiar with the process
4 for manufacturing companies.

5 Q. Are you aware -- but are you aware
6 that -- if you could answer yes or no on that
7 one --

8 A. No, I am not aware.

9 Q. You are not aware of that. So you
10 are not aware that Merck can be sued for
11 injuries caused by the MMR vaccine?

12 A. No.

13 Q. What is a virus?

14 A. A virus is a -- it's an infectious
15 disease particle that can lead to illness of
16 which measles is one example.

17 Q. How does it lead to illness?

18 A. It enters a person's body through
19 different possible routes; it could be
20 respiratory, it could be through the blood,
21 and it can replicate, and it can cause -- it
22 can infect different organs of the body and
23 cause symptoms.

24 Q. Viruses replicate and they take over
25 cells in the body, either they go into DNA or

1 they can enter through their fluids, right?

2 A. Correct.

3 Q. And they can -- the cells -- okay --
4 right. Okay. And usually, the route of
5 infection is actually the mucosal surfaces,
6 right, your eyes, your intestinal tract, your
7 lungs; that's the normal route that a human
8 being would be contacted with a virus,
9 correct?

10 A. That's a common route, yes.

11 Q. Did you discuss your appearance or
12 testimony here today with anybody before
13 today, before this hearing starting?

14 A. Yes, at work, it was discussed that
15 I would be attending here.

16 Q. Who did you discuss that with?

17 A. The people that are in the room.

18 Q. Other than your conversations with
19 counsel, anybody that wasn't an attorney?

20 MR. LEUNG: I am going to just
21 put on the record -- what I am going
22 to do is I am going to allow you to
23 ask relevant questions of the doctor.

24 I understand --

25 MR. SIRI: I am just getting a

1 foundation going. I am taking
2 long --

3 MR. LEUNG: The reason I am
4 cutting this short -- I am asking you
5 to cut this short is I want you to
6 get to the issues regarding the
7 policy. I think you had some policy
8 issues.

9 I don't want this to be a
10 runaround. I know you asked for a
11 deposition of the Commissioner and I
12 am asking you whether or not the
13 doctor --

14 (Indiscernible.)

15 MR. LEUNG: So what I am going
16 to do is just limit your questions to
17 relevancy as to what we are here for,
18 which is the hearing.

19 We have nine other cases. I
20 understand you have to -- I am giving
21 you a lot of leeway. Normally, I
22 don't have hearings that last an
23 hour, we don't have that time, but I
24 am giving you a lot of leeway to ask
25 her questions.

1 Who she spoke to in preparation
2 of this I don't believe is relevant.
3 If you are going to challenge her
4 credibility regarding her knowledge
5 of medical science and things of that
6 nature -- it is not a full-blown
7 trial. We don't have the resources
8 and the time for that. I am going to
9 ask you to get to the relevant
10 questions.

11 MR. SIRI: Can I ask her about
12 her background?

13 MR. LEUNG: You can.

14 Q. Can you tell us about -- just what's
15 your education, what degrees do you hold?

16 A. I have a bachelor in science from
17 Cornell University, an M.D. from Stony Brook
18 Medical Center, I completed a residency in
19 internal medicine at NYU, I completed a
20 fellowship at the CDC as an epidemic
21 intelligence service officer where I worked
22 with Respiratory Diseases branch.

23 I have been at the New York City
24 Department of Health since 2009. I am
25 currently the Director of Epidemiology and

1 Surveillance for the Bureau of Immunizations.
2 We oversee surveillance and outbreak
3 investigations for vaccines, preventible
4 diseases, including measles.

5 Q. Thank you. Now, in the summons, it
6 states that the review of Department of
7 Records, it shows that Respondent, who is at
8 least six-months-old, lives at -- and it
9 provides an address which is located in one
10 of the affected zip codes.

11 How did the Department determine the
12 Respondent's address?

13 A. This person was exposed to --
14 identified as having been exposed to measles.
15 And when an exposure occurs -- so, for
16 example, if somebody is exposed at a medical
17 facility, the address -- the name and the
18 address of the people exposed are provided to
19 the Health Department. So--

20 Q. By the physician's office?

21 A. By the place where the exposure
22 occurred. So, for example, if it was -- if
23 the exposure occurred at an outpatient
24 medical provider's office, the address would
25 have been provided by that provider.

1 Q. And, so, who was providing these
2 names and addresses; was it medical
3 providers, typically?

4 A. A majority of the exposures that
5 occurred did happen in medical settings, so
6 it was the healthcare facility that would
7 have --

8 MR. LEUNG: I will limit the
9 questions to this child, not policy.

10 As to this child, Doctor, do
11 you know how the Department of Health
12 came in possession of his -- this
13 address?

14 MR. SIRI: Sure.

15 THE WITNESS: I don't know the
16 details of where this particular
17 person was exposed.

18 MR. LEUNG: Okay. Counsel,
19 next question.

20 Q. But how did you get the address,
21 from who?

22 A. As I mentioned, I don't know for
23 this particular child, where they were
24 exposed, to have acquired the list of people
25 exposed.

1 So if they were exposed in a
2 healthcare facility, it would have been the
3 healthcare facility.

4 Q. But you don't know the name of the
5 healthcare facility that provided that
6 information?

7 A. We could obtain that; I do not have
8 that.

9 Q. And you don't know -- and just know
10 that you believe that the address came from
11 that unknown facility -- unnamed facility?

12 A. An address would have been provided
13 by the -- at the setting of exposure. I
14 don't know if it was a medical facility but
15 it, for example, if it were, that's where we
16 would have received the initial address.

17 We also have access to the citywide
18 -- the New York Citywide Immunization
19 Registry, which -- in which providers are
20 required to enter vaccination records to all
21 -- for all -- for doses administered to all
22 children in New York City. That's another
23 source of address information.

24 Q. And that registry, does it sometimes
25 have -- is it sometimes missing immunizations

1 that have been administered?

2 A. The vast majority, because it is
3 required by law for providers in New York
4 City to enter doses that were administered,
5 it is highly complete, it is not 100 percent
6 complete.

7 And, so, typically in the setting of
8 an exposure to measles, when people are
9 identified as having been exposed, if we
10 identify a child who doesn't have
11 documentation of immunization, if they had
12 been exposed in a healthcare facility, we
13 would typically reach out to the healthcare
14 facility and ask if they have any
15 supplemental records that haven't been
16 entered into the CIR.

17 We would also try contacting -- we
18 may try contacting the family of the person
19 who is exposed and request additional
20 information.

21 Q. But you don't know the name of the
22 health facility for this Respondent, correct?

23 A. I do not know where this person was
24 exposed.

25 Q. And, so, you are assuming that that

1 happened in this instance, you don't know for
2 sure, correct?

3 A. I know -- I am assuming it was.

4 Q. You are assuming that the procedure
5 that you just outlined, for confirming
6 records, happened in this instance, but you
7 don't know?

8 A. I don't know where this person was
9 exposed. I do know that for every person
10 who's exposed to measles, and who received a
11 summons, before someone receives the summons,
12 they are looked up in the Citywide
13 Immunization Registry.

14 Q. And who did that in this instance?

15 A. One of the staff at the Department.

16 Q. You didn't do it?

17 A. No.

18 Q. What's the name of the Respondent in
19 this case?

20 A. What do you mean, the child or the
21 Respondent?

22 Q. The Respondent. I assume you are
23 not charging the child, but go ahead.

24 A. Malky Tabak.

25 Q. And what's the name of the child --

1 her child?

2 A. We have been going only by initials.

3 MR. LEUNG: I am not going to
4 allow that for privacy reasons. We
5 are going to use initials.

6 Q. Let me ask you this: Do you know
7 the name of the child?

8 A. I do not.

9 Q. Do you know of whether the
10 Respondent's child had moderate or severe
11 acute illness, with or without fever, at the
12 date and time the summons -- the violation
13 listed on this summons?

14 A. I know that we do not have
15 documentation of any contraindication to
16 having been vaccinated.

17 Q. Please answer my question. Do you
18 know whether Respondent's child had moderate
19 or severe acute illness, with or without
20 fever, at the date and time listed on the
21 violation of the summons?

22 A. I do not. But --

23 Q. Do you know whether Respondent's
24 child had a severe allergic reaction after a
25 previous dose of any vaccine?

1 A. We don't have any documentation of
2 such a reaction.

3 Q. Please answer the question. Do you
4 know whether or not Respondent's child had a
5 severe allergic reaction after a previous
6 dose of any vaccine?

7 A. No.

8 Q. Do you know whether Respondent's
9 child had a severe allergic reaction after
10 previous dose of any other drug?

11 A. We don't have any such
12 documentation.

13 Q. Okay. I will ask you again. Do you
14 know whether Respondent's child had a severe
15 allergic reaction after a previous dose of
16 any other drug?

17 A. No.

18 Q. Do you know whether Respondent's
19 child had a severe allergic reaction in the
20 past to a vaccine component?

21 A. We don't have such documentation.

22 Q. Yes or no, please.

23 A. No.

24 Q. Do you know whether Respondent's
25 child is allergic to gelatin?

1 A. We don't have such documentation. I
2 am not aware of this child, no.

3 Q. Are you aware of whether or not the
4 child is allergic to gelatin?

5 A. No.

6 Q. Do you know whether the child is
7 allergic to chicken embryo cells?

8 A. No.

9 Q. Do you know whether the child is
10 allergic to human diploid fibroblasts?

11 A. No.

12 Q. Do you know whether the Respondent's
13 child is allergic to fetal bovine serum?

14 A. No.

15 Q. Do you know whether the child is
16 allergic to neomycin?

17 A. No.

18 Q. Do you know whether the Respondent's
19 child is allergic to sorbitol?

20 A. No.

21 Q. Do you know whether the Respondent's
22 child has severe immunodeficiency or any kind
23 of immunodeficiency?

24 A. No.

25 Q. Do you know whether the Respondent's

1 child has a family history of altered
2 immunocompetence?

3 A. No.

4 Q. Are you aware of whether the child
5 -- the Respondent's child has received,
6 within the last 11 months, any antibody
7 containing blood products?

8 A. No.

9 Q. Are you aware whether the
10 Respondent's child has a history of
11 thrombocytopenia?

12 A. No.

13 Q. Are you aware that the Respondent's
14 child has thrombocytopenic purpura?

15 A. No.

16 Q. Are you aware that all of the items
17 I just listed there are some of the
18 contraindications to the MMR vaccine listed
19 by the CDC and adopted by the New York State
20 Department of Health?

21 A. Some are.

22 Q. Which ones aren't?

23 A. So, you did -- you did list
24 contraindications to vaccination, several of
25 the ingredients that you listed to the

1 vaccine would not cause an allergic reaction.

2 I think your point was to say that a
3 contraindication would be a severe allergic
4 reaction to a vaccine or a component and
5 that's correct.

6 Q. So you are saying that having an --
7 you are saying that it's not a
8 contraindication to be allergic to some of
9 the ingredients in the vaccine that I have
10 just listed?

11 A. I am saying that it is a
12 contraindication if you are allergic to a
13 vaccine component. I am saying that allergic
14 reactions are not expected to all of the
15 ingredients that you just listed.

16 Q. And how do you know that?

17 A. Because we know what common
18 allergies are.

19 Q. When you say "we", who do you mean?

20 A. Common -- common allergies would be
21 to something -- or an allergic reaction could
22 occur typically to something like neomycin or
23 gelatin.

24 Q. And those are contained in the MMR
25 vaccine?

1 A. Correct.

2 Q. But you don't know whether this
3 child has an allergy to those, correct?

4 A. I know that this family did not
5 submit medical documentation.

6 Q. Do you know whether this child had
7 allergic reaction to gelatin or neomycin
8 before this summons was issued?

9 A. I do not.

10 Q. Now, your violation is based on
11 Respondent's not providing the MMR vaccine to
12 their child, correct?

13 A. Correct. And I -- and not
14 submitting documentation of immunity or a
15 medical contraindication.

16 Q. Does the benefit outweigh the risk
17 for injecting the MMR vaccine into this
18 child?

19 A. Based on the information we have,
20 yes.

21 Q. But you don't know whether or not
22 this child has any of the contraindications
23 that we just listed, correct?

24 A. Well, that the -- they were notified
25 that they -- if there were medical

1 contraindication, that that documentation
2 should be submitted.

3 Q. Before the summons was issued, did
4 the Health Department know whether this child
5 had any of the contraindications we just went
6 through?

7 A. No and that's why the family was
8 given an opportunity to submit that
9 documentation.

10 Q. So when the summons was issued, and
11 sitting here today, you don't know whether
12 the child was a contraindication to any of
13 the -- to the MMR vaccine, correct?

14 A. Correct.

15 Q. Okay. So I am going to ask you
16 again. Sitting here today, do you know
17 whether the benefits of the MMR vaccine
18 outweigh the risks for this child?

19 A. Based on the information that we
20 currently have received, yes.

21 MR. LEUNG: I am going to ask
22 you to move on to a different
23 subject. Go ahead. Ask.

24 Q. Did you contact the Respondents to
25 ask if their child had received the MMR

1 vaccine?

2 A. I cannot comment on this particular
3 case.

4 Q. You don't know? I am asking for
5 your knowledge. You are here testifying
6 on --

7 A. Yes, I know that we do not have any
8 documentation of vaccination or a medical --

9 Q. I am asking: Did you contact the
10 Respondent to ask if their child had received
11 the MMR vaccine?

12 A. I did not.

13 Q. Do you know -- do you have specific
14 knowledge of somebody at the Health
15 Department contacting the Respondent to ask
16 if their child had received the MMR
17 vaccination?

18 A. I -- I don't have access to that
19 information right now, it is possible that
20 someone from the Health Department called the
21 family.

22 Q. But you don't know?

23 A. We can -- we can confirm that, I
24 just --

25 Q. But I am asking -- but you don't

1 know, right?

2 A. I do not know.

3 Q. Did anybody from the Health
4 Department contact this Respondent to ask if
5 their child is a contraindication to the MMR
6 vaccine?

7 MR. LEUNG: Let me just say,
8 Doctor, to the best -- to your own
9 personal knowledge, you can't speak
10 to anyone else, just to your own
11 personal knowledge.

12 I am going to ask to take a
13 break. Just give me two seconds. I
14 am just going to pause the hearing
15 for a second.

16 (Whereupon, a brief recess was
17 taken at this time.)

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C E R T I F I C A T E

I, JACQUELINE N. FAUGHT, a shorthand reporter and Notary Public within and for the State of New York, do hereby certify:

That the witness(es) whose testimony is hereinbefore set forth was duly sworn by me, and the foregoing transcript is a true record of the testimony given by such witness(es).

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

JACQUELINE N. FAUGHT

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* E R R A T A *

CASE NAME:

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WITNESS SIGNATURE

SUBSCRIBED AND SWORN TO BEFORE

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NYC OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS

COUNTY OF NEW YORK

- - - - - x

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL

HYGIENE,

Petitioner,

Summons No. 30198-19L0

-against-

MALKY ROTH TABAK,

Respondent.

- - - - - x.

66 John Street
New York, New York

August 28, 2019
10:11 a.m.

B E F O R E:

HONORABLE DAVID LEUNG.

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MR. LEUNG: Let me just say,

3

Doctor, to the best -- to your own

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personal knowledge, you can't speak

5

to anyone else, just to your own

6

personal knowledge.

7

I am going to ask to take a

8

break. Just give me two seconds. I

9

am just going to pause the hearing

10

for a second.

11

(Whereupon, a brief recess was

12

taken.)

13

MR. LEUNG: Okay. The record

14

should reflect that I stepped out,

15

spoke to a hearing supervisor, and

16

now I'm back in. Go ahead, counsel.

17

MR. SIRI: Okay. Thank you.

18

EXAMINATION BY

19

MR. SIRI:

20

Q. Doctor, does the MMR vaccine

21

involve an injection into the body?

22

A. I would like to go back to your

23

question.

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Q. Your attorney -- when I'm

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done --

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MR. MERRILL: Yeah.

MR. SIRI: When I'm done you
can redirect.

MR. LEUNG: Two things.
Counsel, I don't mean to cut you
short.

MR. SIRI: Yes.

MR. LEUNG: We have other
hearings. What I'm going to ask you
is, your overall argument here in
this line of questioning is that it
wasn't medically necessary for this
child or --

MR. SIRI: That's one of the
reasons under the order is that
whether it was medically appropriate
and I seek to establish here today.
Yes. But I need the opportunity to
establish that factual record, your
Honor. Without establishing it, I
don't know how you can rule on -- on
that point.

MR. LEUNG: Okay. Normally,
you would establish that record by

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bringing in evidence. In other words --

MR. SIRI: You want to put the burden on my client?

MR. LEUNG: No. No. No. I'm not putting the burden, but the issue is that you were served a summons that said there was no proof of immunization or proof of immunity or proof of a medically -- a medical exemption. So those are the three allegations here. No immunization, no proof of immunity, and no --

MR. SIRI: It doesn't say anything about a medical exemption in the violation in the last sentence. But even if it did, I certainly should have the opportunity to present a defense that it wasn't medically appropriate. How can I not?

MR. LEUNG: No. No. You can present a defense. All I'm saying is that if you ask her questions and she

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says -- you know what, I'm going to
let you continue. Go ahead.

MR. SIRI: Thank you, your
Honor.

Q. Does the MMR vaccine involve an
injection into the body?

A. Yes.

Q. What company manufactures the
MMR vaccine in the United States?

MR. LEUNG: Okay. That's what
I'm talking about. How is that
relevant to the hearing?

MR. SIRI: They are ordering --
she testified that an injection of
this product into my client's body --
you don't think that in understanding
that product, its risks, its
benefits, is relevant to whether it's
moderately appropriate to require
that injection?

MR. LEUNG: The issue right now
is whether or not -- I understand
your overall argument in terms of
constitutional arguments --

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2 MR. SIRI: No. No. Not only
3 that constitutional argument. The
4 order provides it should be medically
5 appropriate. So All right -- I am
6 seeking to establish that it was
7 medically appropriate.

8 MR. LEUNG: Okay. Let me just
9 take a look here, real quick, of what
10 the order says. Because what's going
11 to happen here is --

12 MR. SIRI: So your saying that
13 there is no medical exemption given
14 this order? Your saying that this
15 child has to get it no matter what?

16 MR. LEUNG: No. No. No. I'm
17 saying that you are served with a
18 summons and that they are --

19 MR. SIRI: I understand.

20 MR. LEUNG: The summons
21 established that -- okay. The
22 summons established a prime facia
23 case against your client that they
24 didn't get immunized as ordered by
25 the Commissioner. Or in the

1
2 alternative, show proper immunity to
3 the measles or a proper medical
4 exemption. We're here for that
5 hearing now. The summons alleges
6 that.

7 So their saying that your
8 client didn't do any of those three
9 alleged things. Getting immunized,
10 show proof of immunity --

11 MR. SIRI: Even if I accept
12 everything you just said, your
13 Honor --

14 MR. LEUNG: No. It's an
15 allegation. I'm not saying accept
16 it. I'm just saying that's what the
17 summons alleges.

18 MR. SIRI: Right. Well, if the
19 summons does allege that, though I
20 will say it says, failed to vaccinate
21 or provide proof of immunity. But
22 let's just say that it also failed to
23 provide, you know, medically -- you
24 know, that it is not medically
25 appropriate, which doesn't say that

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in the last sentence.

MR. LEUNG: Okay. Right.

MR. SIRI: This, I'm seeking to establish that right now.

MR. LEUNG: Establish what?

MR. SIRI: That it's not medically appropriate.

MR. LEUNG: Medical exemption --

MR. SIRI: Your using the term "medical exemption." It says, medically appropriate.

MR. LEUNG: Okay. What I'm going to do is, your making an argument that it is not medically appropriate for this client. Well, I'm asking you to say it. You can testify, you can say affirmatively what these questions are that your trying to establish, which is that there may have been an adverse reaction to certain ingredients. But what your trying to establish is that, she doesn't know whether or not

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he does or not. Which establishes --
what I'm trying to --

MR. SIRI: Well, moving on from
there already.

MR. LEUNG: Yeah.

MR. SIRI: I'm just going to
move onto other stuff.

MR. LEUNG: What I'm trying to
do is -- what I'm doing is -- what I
have been told by my supervisor is,
you need to move on because if these
are not -- what I'm trying to do is,
prevent the other nine from being
defaulted. What their saying, is
that time is of the essence in terms
of getting these down.

MR. SIRI: Look, I've got to
put a proper defense. I just can't
stress enough, you know --

MR. LEUNG: I think this
hearing began over an hour ago, sir.

MR. SIRI: Your -- these people
are just living in their homes.

MR. LEUNG: Now, I

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understand --

MR. SIRI: They're just
existing.

MR. LEUNG: I understand that.

MR. SIRI: And their in
violation for existing --

MR. LEUNG: Right.

MR. SIRI: -- as God created
that. That's literally what we're
talking about here today.

MR. LEUNG: I know.

MR. SIRI: If I -- I need to be
able to make a proper record, not
only for this hearing, but also for
appeal.

MR. LEUNG: And I think I've
given you the opportunity to make a
proper record.

MR. SIRI: I would say I have
not even touched on the medical
appropriateness then.

MR. LEUNG: Well, I'm going to
ask you --

MR. SIRI: But you know, I --

1
2 you know, I would say that -- let's
3 look at it this way, if you can carry
4 over the record from here to the
5 other hearings, that will make it --
6 but I need an opportunity to make my
7 record.

8 MR. LEUNG: You can make your
9 record. You can ask a couple of more
10 questions and then we're going to
11 have to move along.

12 MR. SIRI: I got to object to
13 that.

14 MR. LEUNG: You can object to
15 anything you want.

16 MS. PEONE: I'm sorry. Can I
17 just --

18 MR. SIRI: I know. I'm just
19 putting on the record my objection
20 that I have not been given enough --
21 asking just a few more questions is
22 not, you know -- I strenuously object
23 because I'm not being provided an
24 opportunity to create a record.

25 MR. LEUNG: I understand your

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objection, counsel.

MR. SIRI: Okay.

Q. All right. So again, what companies manufacturer the MMR vaccine that this order says my client should be injected with?

MR. LEUNG: You can answer that. Go ahead.

A. Merck.

Q. Merck?

A. Yes.

Q. They're the only manufacturer, correct?

A. I can't comment on that.

Q. Do you know when the MMR vaccine was licensed?

MR. LEUNG: Counsel, I'm going to stop it here because I don't -- you can make your ultimate argument. If your ultimate argument is that you believe this MMR --

MR. SIRI: How can I make an ultimate argument without a factual record, your Honor.

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MR. LEUNG: Because what we're doing right now --

MR. SIRI: You want me to just say into the ether that it's not medically appropriate? How do I do that without a factual record?

MR. LEUNG: You can ask the doctor and you can establish --

MR. SIRI: You want me to just say is it medically appropriate?

MR. LEUNG: Well, what is your basis? You can make --

MR. SIRI: I'm trying to establish that.

MR. LEUNG: Your trying to establish what?

MR. SIRI: That it's not medically appropriate, but I need to be given an opportunity to question the doctor.

MR. MERRILL: I object to the term "medically appropriate." That's not in the order anyway.

MR. LEUNG: Well, I --

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MR. SIRI: It's in the violation. It's in the summons.

While your looking at that, can I just ask a few more questions?

MR. LEUNG: Go ahead.

MR. SIRI: Okay.

Q. Well, I'm going to -- I'll try to make this quicker. Can the MMR vaccine cause brain damage?

A. Serious allergic -- serious reactions to the MMR vaccine is very rear.

Q. Please answer the question. Can the MMR vaccine cause brain damage? Yes or no?

A. That is not a typical reaction of the MMR vaccine.

Q. Can the MMR vaccine cause brain damage? Yes or no?

MR. LEUNG: Okay. Counsel, I'm going to just -- the reason why I'm doing this --

MR. SIRI: Can I make an application to have a deposition and we can come back another day?

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MR. LEUNG: Yeah. First off --

MR. SIRI: After I've had an
opportunity to figure out --

MR. LEUNG: This is the offset
of a trial hearing. It is not a full
blown hearing. It's not a full blown
trial. So the procedures are
streamlined for an efficiency and to
get to the facts.

MR. SIRI: I don't --

MR. LEUNG: There's no
provisions for depositions.

MR. SIRI: Okay. Okay. So
your denying the application?

MR. LEUNG: I'm denying the
application. Yes.

MR. SIRI: That's fine. Okay.
So I'd like to continue to question
the witness.

MR. LEUNG: Okay. I'm going to
rule and I don't mean to -- counsel,
let me just establish -- I don't even
know what time this hearing started.
It's almost noon now. I think its

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been over an hour. You have nine other cases.

The issue that I'm going to read here is the following: On page 2 of the order that is at issue here in the summons, is that the child should be vaccinated against measles and such parent or guardian shall demonstrate that the child has immunity or document to the satisfaction of the Department that said child should be medically exempt from this requirement. So questions right now regarding whether or not the -- who made the MMR vaccine, does it cause X, Y, and Z damages done, does not go to the issue of whether or not the child had immunity, whether he had the proper vaccination, or whether he was medically exempt.

MR. SIRI: Really? Why not?

MR. LEUNG: Because medically exempt is an issue, an affirmative

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defense that you can raise by
producing evidence, that my client is
medically exempt for X, Y, and Z
reasons and here's a doctor's note.
Or here's my document that says that
it's medically exempt. It's not by
asking questions that can be negated
by this -- negated by this doctor
saying no to every question you ask.
It doesn't establish the medically --

MR. SIRI: But your assuming --
you just assumed that --

MR. LEUNG: I'm not assuming
anything. No. No.

MR. SIRI: They're not just --

MR. LEUNG: I'm assuming based
upon the chain of questions and the
questions that I've allowed that I
should have stopped. Such as, who
makes the vaccine. I mean, that's a
discovery question for counsel in a
civil litigation. It has nothing to
do with whether or not the child was
vaccinated.

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MR. SIRI: Whether it's a predicate to the documentation that shows?

MR. LEUNG: Do you --

MR. SIRI: I have plenty of documentation.

MR. LEUNG: Are you having Merck --

MR. SIRI: I wanted to establish --

MR. LEUNG: Counsel, do you have documentation showing whether or not this child is medically exempt from the requirement or has the proper immunity?

MR. SIRI: Yes. All of this over here shows that this child should not receive the MMR vaccine and I need to go through it with this document and establish that.

MR. LEUNG: Okay. So all of those documents show what? Just tell me what it shows.

And the record should reflect

1
2 that counsel is pointing to a box
3 full of documents. What will those
4 documents show? Just give an offer
5 of proof.

6 MR. SIRI: Sure. The offer of
7 proof shows that the risks of the MMR
8 vaccine outweigh the benefits for
9 this child.

10 MR. LEUNG: Okay. And how does
11 that address the following issues:
12 Whether or not the child was
13 vaccinated, whether or not the child
14 had the proper immunity, or whether
15 or not the child was medically
16 exempt?

17 MR. SIRI: Should be medically
18 exempt because the risks outweigh the
19 benefit.

20 MR. LEUNG: Okay. And it's
21 through questioning and -- what
22 documents do you have to show that --

23 MR. SIRI: I have the clinical
24 trials of the MMR. I've got all
25 kinds of documents regarding the

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product.

MR. LEUNG: Please testify in a summary fashion as to what your evidence will show. Because I want that to be in the record and I don't want to exclude your evidence, but I'm not going to allow you to question this doctor as to every chain of science leading up to whether or not the MMR vaccine is or is not safe.

MR. SIRI: Well, your assuming what I was going to ask.

MR. LEUNG: I'm not assuming anything. I'm just trying to expedite this hearing to give you a fair hearing and also to allow you to --

MR. SIRI: Is she going to get to respond to what I say?

MR. LEUNG: It doesn't --

MR. SIRI: Well, in that case, it's totally unfair and prejudicial. What your saying to me is, I need to

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basically preview to the witness all of the arguments so that she can then be coached -- coached as to what she's going to say.

MR. LEUNG: No. No. No.

Because this is a hearing --

MR. SIRI: Doctors should have to --

MR. LEUNG: Counsel, let me just speak.

MR. SIRI: Yeah. I wanted to finish my argument.

MR. LEUNG: Because this is a expedited hearing in terms of us getting to the facts. It's not a trial. The rules of evidence are relaxed. I'm going to ask you to get to the substance of what your evidence will show and I'm giving you an opportunity to summarize it without asking 100 questions to the doctor. So before I close the hearing, I'm going to give you an opportunity.

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MR. SIRI: I probably could have gotten through half of my outline already.

MR. LEUNG: Okay. But it we have been on this hearing for over an hour now and we have nine additional hearings.

MR. SIRI: So --

MR. LEUNG: I'm sorry.

MS. DIRECTOR: Can you pause the audio so I can address all the parties.

MR. LEUNG: Let me just pause that real quick.

MS. DIRECTOR: All right.

MR. LEUNG: It's not paused. Hold on. I'll tell you when it's paused.

MS. DIRECTOR: All right.

(Whereupon, a brief recess was taken.)

MR. LEUNG: Okay. The record should reflect we're back on the record. We spoke with the assistant

1
2 director of adjudication, who came in
3 and determined that the substantive
4 argument regarding constitutional
5 arguments that have taken up a
6 significant amount of this hearing,
7 can be transferred over to the
8 subsequent hearings. And we're going
9 to -- in the other eight hearings
10 reference the argument regarding
11 that.

12 Counsel, Mr. Siri.

13 MR. SIRI: Yes.

14 MR. LEUNG: As to the other
15 eight subsequent hearings, to the
16 extent obviously they're all
17 individualized with different
18 children or individuals, you can make
19 your defenses individually just like
20 you did in the beginning of this.

21 MR. SIRI: Right.

22 MR. LEUNG: When we get to this
23 portion of the argument, you can just
24 tell me on the record that your
25 referencing the same arguments.

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MR. SIRI: Absolutely.

MR. LEUNG: Okay.

MR. SIRI: Gotcha.

MR. LEUNG: So --

MR. SIRI: And those others
should go a lot quicker. Very
quickly.

MR. LEUNG: And Mr. -- when we
last spoke before I paused the
record, what I was doing is, I was
cutting you off in the politest way
possible, from asking additional
questions of this doctor to establish
your offer of proof that the MMR
vaccine, in your opinion, and this is
the substance of your question, the
benefits -- the health benefits do
not outweigh the health risks and
dangers of the MMR vaccine.

And you were going to ask
questions of this doctor to establish
that. What I was trying to tell you
that you don't need to ask her
questions. You can assert

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affirmatively what you believe
through your evidence. Okay.

MR. SIRI: I understand. I
just, for the record --

MR. LEUNG: Yeah.

MR. SIRI: Their the one who
issued the violation.

MR. LEUNG: That's true. I
don't mean to cut you off. That's
true. However, you are asserting the
affirmative defense of, Hey, this
summons doesn't apply to me because I
know this child doesn't have the
vaccine. And I know there's nothing
in his record, and I'm assuming that
it is a him, that shows that he has
the immunity, but it's not
medically --

MR. SIRI: With the Health
Department --

MR. LEUNG: He should be
medically exempt. Now, medically
exempt is -- I'm going to ask the,
Doctor.

1
2 What does medically exempt and
3 what is the proof required for a
4 medical exemption according to the
5 statute in the Department of Health.

6 MS. ROSEN: So a provider would
7 submit documentation stating that a
8 person has a contraindication to
9 receiving the MMR vaccine and there
10 are standard criteria. The Advisory
11 Committee on the Immunization
12 Practices and we have a copy of the
13 summary outlines what
14 contraindications are to different
15 vaccinations.

16 MR. LEUNG: And is this a --
17 this has to be a letter from a
18 physician.

19 MS. ROSEN: You want to pull up
20 the wording from --

21 MR. SIRI: That is not what it
22 says in the -- this doesn't say
23 anything about a letter from a
24 physician.

25 MR. LEUNG: I understand that.

1
2 I'm just asking what the
3 definition of that term "medically
4 exempt," what is that.

5 MS. ROSEN: This would not be
6 -- this would not come from -- it's
7 not a parent's decision about having
8 a contraindication. It would be
9 coming from a medical provider who
10 deems this person to have a medical
11 contraindication and that
12 contraindication should be valid
13 based on the Advisory Committee on
14 Immunization Practice national
15 standard.

16 MR. LEUNG: And Doctor, in your
17 experience in dealing with MMR cases,
18 what has been an acceptable
19 medically -- what has been determined
20 as being medically exempt? Accepting
21 proof of medical exemption.

22 MS. ROSEN: So criteria would
23 include somebody who's pregnant.
24 There are very few contraindications
25 to the MMR vaccine.

1
2 Contraindications include pregnancy,
3 someone who is severely
4 immunocompromised. That would, for
5 example, include somebody perhaps
6 who's on chemotherapy, or cancer
7 treatment, somebody who has a severe
8 allergic reaction to a vaccine.

9 A document -- someone who has
10 documented severe allergic reaction
11 to a vaccine that they have received
12 or a vaccine component previously
13 documented to a severe allergic
14 reaction. When we say, severe, that
15 means something that is threatening.
16 Something like anaphylactic reaction
17 or someone can't breathe. Not a
18 rash, for example.

19 MR. LEUNG: So the child cited
20 in the summons -- and I don't mean --
21 I just have to. As to the child
22 cited in the summons, you do not know
23 for certain whether or not this child
24 has these contraindications or does
25 not have it; is that correct?

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MS. ROSEN: We're left to assume that don't, because they did not submit documentation, as that line in the summons showing that they have the medical contraindication. Medical contraindications are very rear. Most people are eligible to receive the vaccine.

MR. LEUNG: Mr. Siri, can you ask your questions of the Doctor that go to the issue of medical exempt --

MR. SIRI: Sure.

MR. LEUNG: -- as it's defined?

MR. SIRI: Sure.

Q. Can the MMR vaccine cause brain damage?

A. That is not an expected reaction to that MMR vaccine.

Q. Can it cause brain damage?

A. It's not an expected reaction.

And given the person's background, the safety of vaccines is monitored very closely. Millions of doses of this vaccine has been given as a routinely recommended

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vaccine.

MR. SIRI: I mean, can you direct the witness to answer the question?

MR. LEUNG: I'm going to allow it.

MR. SIRI: It's kind of difficult because it takes a while because I don't get an answer.

MR. LEUNG: Well, I'm going to ask you this: I allowed that question, but how does that go to the issue of medically exempt? Because medical exempt based upon what the doctor testified to is a doctor's note. I mean, I'm just going to lay out, it's a doctor's note from the child's physician saying that the child's medical condition, as it existed at the time, the doctor wrote the note exempts the child because of some condition.

So how does this question establish that?

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2 MR. SIRI: You know, your
3 Honor, under the City Charter --
4 okay. It provides that the City
5 Charter says that -- and this is
6 Section 10495. It says that an
7 administrative law judge appearing --
8 officer, may dismiss a Notice of
9 Violation when in interest of
10 justice. And then it goes onto give
11 criteria.

12 MR. LEUNG: Okay. So --

13 MR. SIRI: So there's also --
14 I'm just adding on that there's also
15 an interest of justice here. And
16 that's a proffer argument that I can
17 make under the City Charter and all
18 of this also goes to that.

19 MR. LEUNG: Okay. I understand
20 that, but what I'm trying to tell you
21 is, that I'm asking you to restrict
22 your questions to the issue of
23 medically exempt. You can make the
24 argument and you can testify as to
25 why you believe an interest of

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justice of dismissal is appropriate.

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However, your asking questions such

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as, you know, who makes it? That

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doesn't go to the --

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MR. SIRI: I'm just asking if

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the MMR can cause brain damage.

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MR. LEUNG: And I'm allowing

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her to answer the way it is. I'm not

10

going to --

11

Q. Can the MMR vaccine cause

12

deafness?

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A. I'm not aware of the vaccine

14

causing deafness.

15

Q. Can the MMR vaccine cause long

16

term seizures?

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A. I'm not aware --

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MR. LEUNG: Counsel, again --

19

MR. SIRI: I'm almost done.

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I'm almost done on that one. I'm

21

going to give you evidence right now.

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MR. LEUNG: Go ahead.

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MR. SIRI: I'm going to give

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you evidence right now. I just --

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Q. Can the MMR cause --

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MR. SIRI: I can go fast. I just need to give it some --

MR. LEUNG: What I'm going to do right now, counsel, I know your going fast, but I'm going to stop you there. I'm going to stop you there because again, it's not addressing the issue of whether this child --

MR. SIRI: How do you know? I haven't asked my questions.

MR. LEUNG: Because I've given you a lot of leeway.

MR. SIRI: I've really not got to ask any questions. We've spent like 40 minutes arguing about asking questions. I haven't got to ask many questions.

MR. LEUNG: The question that you just asked -- forget about the line of questioning. The question that you just asked does not -- the specific questions that you just asked, does not go to the issue of whether or not this child has a

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medical exemption.

MR. SIRI: It goes to whether or not the summons is appropriate if they don't know the condition of the child beforehand, they don't understand what the vaccine -- they don't understand what the vaccine can cause. What reactions it causes. How can they issue this order? Of course it's appropriate. They need to understand what medical issues the vaccine causes. What the condition of the child is. And if they don't know, how are they issuing the summons?

MR. LEUNG: Again, your question then --

MR. SIRI: It goes to injustice.

MR. LEUNG: Your question then goes to the issue of why this summons issued have been issued in the beginning, which -- you just told me --

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MR. SIRI: Their both. Their both.

MR. LEUNG: Okay.

MR. SIRI: I know you want to restrict it to that particular point, but I actual have other arguments including injustice of the Charter. There's that.

MR. LEUNG: I understand. And one of your arguments that you just made is that you asked a question because you believe this summons was improperly issued to begin with. That they had no basis to issue the summons.

MR. SIRI: That's right.

MR. LEUNG: And again, I'm going to deny your request to ask that question because that doesn't go to the issue that I ultimately have to decide. I'm not going to decide whether or not there was a good cause basis to issue the summons. I'm going to tell you straight up. I'm

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not going to do that.

MR. SIRI: And I get that.

MR. LEUNG: So the question is not relevant for me making that decision. So I'm going to stop you there and I'm going to ask --

MR. SIRI: But it is relevant to the question of injustice --

MR. LEUNG: I'm going to stop you there.

MR. SIRI: -- under the Charter that you can argue the ruling.

MR. LEUNG: I understand. You've asked the questions and I've allowed them and I understand your argument.

MR. SIRI: Really? I haven't asked my questions.

MR. LEUNG: And your argument is that the summons does not conform to the interest of justice. And your line of question -- and your line of questioning goes to that. I understand that.

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MR. SIRI: Can I -- let me ask some questions -- quick questions. Okay. Honestly, I could have gotten through a lot of this already, you know. So let me just -- here. I'll put this into evidence (handing).

MR. LEUNG: What is this? What are you handing me?

MR. SIRI: This is from the CDC. This is something called a vaccine information statement.

MR. LEUNG: Respondent's 2. I've marked and I'm going to show it to counsel for Department of Health (handing).

MR. SIRI: Here's a copy. Okay. Can I just see --

MR. LEUNG: Read that and let me know. Hearing no objections, it'll be admitted.

MR. SIRI: And this vaccine information statement published by the CDC provides that risks of the MMR vaccine include deafness, long

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term seizure, coma, and brain damage.

Okay.

MR. LEUNG: As the hearing
officer --

MR. SIRI: I'm going to tie it
all back to the client.

MR. LEUNG: As the hearing
officer, I am taking that testimony
in and I am considering this in my
decision. You have just testified to
something that is relevant. Your
saying that there is a federal CDC
printout that shows that there is a
danger to this MMR vaccine.

And ultimately that issue goes
to what about this summons that your
saying that it addresses?

MR. SIRI: It's not appropriate
to issue it.

MR. LEUNG: I'm sorry. Just --

MR. SIRI: But it needs to be
-- that the summons was unjust to
issue, but not in a vacuum.
Obviously, that alone --

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MR. LEUNG: Does it go other than to --

MR. SIRI: -- to the injustice.

MR. LEUNG: Does it go to the issue of whether or not there's a medical exemption?

MR. SIRI: It goes to the medical exemption. It goes to the appropriateness of the violation.

MR. LEUNG: How does it go to the medical exemption? Just explain it to me so I can --

MR. SIRI: Well --

MR. LEUNG: How does the CDC outline or whatever this form is go to the issue of medical exemption?

MR. SIRI: It goes to the question of whether or not at the end of the day -- if you look -- when you look at the violation itself -- okay. On the violation it says -- it says, "Document to prove that the immunization is not medically appropriate." Okay.

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MR. LEUNG: Where are you reading?

MR. SIRI: I'm reading from the violation itself.

MR. LEUNG: The summons.

MR. SIRI: The summons.

MR. LEUNG: Okay.

MR. SIRI: So I'm trying to provide you the documentation, including through testimony --

MR. LEUNG: Okay. But that's --

MR. SIRI: -- is not medically appropriate. I know what you want. You want me to get some doctor's note to do that.

MR. LEUNG: No. Medical -- there are two different stances. What's written on the summons isn't what I have to decide. What I have to decide is whether or not the law -- the order was complied with in the sense that the child was either vaccinated, had the proper immunity,

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2 or was medically exempt. And what
3 your showing me -- what I'm trying to
4 do is -- I'm not denying you
5 presenting evidence.

6 What I'm trying to say is, that
7 what your giving me, tie it into one
8 of those three things. Oh, an
9 interest of justice.

10 MR. SIRI: An interest of
11 justice is off --

12 MR. LEUNG: When you give me
13 some -- all I'm asking is --

14 MR. SIRI: Okay.

15 MR. LEUNG: -- what pigeon hole
16 are you putting this into?

17 MR. SIRI: Understand.

18 MR. LEUNG: Are you putting it
19 into the interest of justice pigeon
20 hole or are you putting this into the
21 -- that's all I'm asking.

22 MR. SIRI: Interest of justice
23 appropriateness of the summons.

24 MR. LEUNG: Okay.

25 Appropriateness of the summons is

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something that --

MR. SIRI: Yeah. So there's
three.

MR. LEUNG: Okay.

MR. SIRI: There's interest of
justice.

MR. LEUNG: Okay.

MR. SIRI: There's
appropriateness of the summons
because you have to have a factual
background. Meaning, they have --
she should have basic knowledge
regarding the product their saying
the child should be injecting with
and the child.

MR. LEUNG: Okay.

Appropriateness of the summons.

MR. SIRI: And the third is --

MR. LEUNG: Interest of
justice.

And what's the third?

MR. SIRI: And medically
appropriate.

MR. LEUNG: Medically

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appropriate.

MR. SIRI: What are you calling
medical exemption? Whatever you want
to call it.

MR. LEUNG: Okay. Okay.
That's fine.

MR. SIRI: And the interest of
justice has a subpoint that they have
not -- that, you know, I'm going to
present you -- they can't
substantiate that the risks -- that
the benefits outweigh the risks.

MR. LEUNG: Okay.

MR. SIRI: I'm going to
substantiate that.

MR. LEUNG: I've let you make
the argument.

MR. SIRI: Yes.

MR. LEUNG: Yet the benefit
does not outweigh the risk.

MR. SIRI: Yes.

MR. LEUNG: And I've allowed
you to present some documents.

Is there any other documents

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you want to present or any evidence
that you want to present?

MR. SIRI: Yes.

MR. LEUNG: Okay. Go ahead.

MR. SIRI: Okay. So the next
document I'm going to present
requires a little bit of testimony.
Probably four questions.

Can I ask the witness?

MR. LEUNG: What are the basis
of the questions? I mean, I just --
go ahead. Start your questioning.

MR. SIRI: Okay. Just so we
know what we're talking about here --
all right. I just want to make sure
we're on the same page with what
we're talking about.

Q. This is a MMR vaccine
container, right?

A. Correct.

MR. LEUNG: Let the record
reflect that Mr. Siri is holding up
an MMR container.

Q. And this is a dose of MMR? One

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dose that you would give to one child,
correct?

A. It's a vial of MMR vaccine.

Q. That would be administered to a
child under the order, to comply with the
order, this is what they would need to be
injected with, correct?

A. Correct.

Q. This is -- and this is -- so
you can see what it is. This is a vial of
MMR without the label on it so you could
see it's actually in powder form. This
powder form encounters liquid solution
before it's injected, right?

A. Correct.

Q. Okay. And this is the typical
needle that you use to do that?

A. Correct.

Q. I'm going to use the
appropriate procedure for putting it back
on. I think I did that right. That's an
unopened one. Okay.

Before this product is licensed
in 1978 it underwent a clinical trial,

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right?

MR. LEUNG: I'm going to --

MR. SIRI: Three more
questions.

MR. LEUNG: No. No. Counsel,
I'm stopping you right there.

MR. SIRI: Let me get back to
the clinical trial.

MR. LEUNG: Get to your
testimony.

MR. SIRI: Give me Exhibit 175.
I don't know how I can do this
without testimony. But I mean, I'm
just going to object for the order.

MR. LEUNG: You can object,
counsel. You can put your objection
on the record.

MR. SIRI: Not 175.
Exhibit 317.

Q. As the exhibit is being pulled
out, to have a proper clinical trial you
need thousands -- tens of thousands of
participants to see significant results,
correct?

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2 MR. LEUNG: Counsel, I'm going
3 to object. Counsel, I'm not going to
4 let you ask her the foundation of how
5 the MMR vaccine came into existence,
6 the clinical trials, the positives
7 and negatives of it.

8 MR. SIRI: Why not? Doesn't
9 that go to all four of the points we
10 just talked about.

11 MR. LEUNG: No. No. I'm going
12 to allow you to tell us -- I'm going
13 to allow you to submit evidence as to
14 that.

15 MR. SIRI: Okay. But she -- so
16 if that -- if I'm going to do it that
17 way, I want to make -- I want a
18 directive that she doesn't have an
19 opportunity to actually then opine on
20 it. Because what's going to happen
21 is --

22 MR. LEUNG: Counsel, I'm not
23 going to make a preliminary ruling as
24 to what another witness can and
25 cannot do. I'm not going to bar them

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2 from doing that. You can make an
3 application at the end of your
4 presentation. If they start talking,
5 then you can say that's
6 inappropriate. I don't want them to
7 talk and I'll make an application,
8 but you can't bar them. I can't put
9 a restriction --

10 MR. SIRI: But your barring me
11 from asking her questions.

12 MR. LEUNG: No.

13 MR. SIRI: But you don't want
14 to bar her from --

15 MR. LEUNG: I'm not.

16 MR. SIRI: Okay. I'm fine with
17 -- if you want to bar me from asking
18 questions, I will offer my proffers
19 of proof.

20 Can I just make an objection on
21 the record?

22 MR. LEUNG: No. No.

23 MR. SIRI: But I would like
24 similar directives that counsel for
25 the DOH cannot also ask questions.

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MR. LEUNG: Let me just put on record, I'm not barring you from asking questions. I'm barring you from asking questions that are not relevant.

MR. SIRI: Then go to the four points.

MR. LEUNG: I understand you disagree with me.

MR. SIRI: Yes.

MR. LEUNG: You think their relevant.

MR. SIRI: I'm just making --

MR. LEUNG: I --

MR. SIRI: I'm just making a record.

MR. LEUNG: I understand.

MR. SIRI: I'm just making a record.

MR. LEUNG: I'm barring you from asking questions, and I've given you a lot of leeway, that I believe is not relevant to my ultimate determination as to the facts of this

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2 case. That's what I'm barring you
3 from. I'm not barring you summarily
4 from asking questions because A, I
5 don't like you or B, because --

6 MR. SIRI: And I think you did.

7 MR. LEUNG: No.

8 MR. SIRI: You seem very nice.

9 MR. LEUNG: I'm barring you
10 because I believe the line of
11 questioning is not relevant. Simple
12 and that's it. Nothing personal.
13 And to the extent that your telling
14 me that they cannot ask questions, I
15 don't even know what the questions
16 are. If it's not relevant, then I'll
17 bar them. But if it is relevant,
18 then I'll allow it. Your telling me
19 to put a gag order on them before
20 they can go.

21 MR. SIRI: Yeah.

22 MR. LEUNG: What I'm telling
23 you right now is, that you can
24 present evidence. Any evidence you
25 want. I'm not barring you from

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2 anything. But if you ask questions
3 that are not relevant, I'm going to
4 stop you and I've given you a lot of
5 leeway.

6

MR. SIRI: Okay. I hope the
7 same standard of relevance that your
8 applying.

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MR. LEUNG: It will.

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MR. SIRI: It will apply to
11 them too?

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MR. LEUNG: It will. I
13 guarantee it.

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MR. SIRI: Because I can't see
15 what possible questions can be asked.

16

MR. LEUNG: I guarantee it
17 will. And to the extent that you
18 believe that they asked questions
19 that are not relevant, you object and
20 I'll make the ruling.

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MR. SIRI: So any questions
22 regarding the safety or advocacy is
23 not relevant, right?

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MR. LEUNG: Safety or evidence.

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MR. SIRI: Okay. This is a

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copy of the clinical trial summary by
the FDA --

MR. LEUNG: How many pages are
in that, counsel?

MR. SIRI: 214.

MR. LEUNG: Okay. So what are
you giving that to me for?

MR. SIRI: This --

MR. LEUNG: So what's the
purpose? Where's the cover letter?
Where does it go.

MR. SIRI: Yeah. This goes
into all four of the arguments.

MR. LEUNG: Okay.

MR. SIRI: All four.
Everything that I'm going to give you
right now goes into all four of those
arguments.

MR. LEUNG: This 200 plus page
document will be marked as
Respondent's 3 -- I'm sorry
Respondent's 4.

MR. SIRI: You know, do we have
a summary?

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MR. LEUNG: Did you give me
three separate documents of this or
just one?

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MR. SIRI: No, your Honor.
Just one.

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MR. LEUNG: Just one. Okay.
So this is Respondent's --

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MR. SIRI: 317.

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MR. MERRILL: Do you have a
copy for me?

11

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MR. SIRI: You know what, I got
just the relevant trials from that.
I can give you a shorter version.
Would you prefer that?

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MR. LEUNG: Give me whatever
you want, counsel.

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MR. SIRI: Okay.

18

MR. MERRILL: Can I just ask
what this is?

19

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MR. SIRI: No. 368.

21

MR. LEUNG: Can you summarize
what this 200 page document is?

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23

MR. SIRI: That is the FDA
Summary of the Clinical Trials relied

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upon to license the MMR II vaccine that the order is saying should be injected into my client.

MR. LEUNG: And make an argument for me. As the finder of fact, what is the -- what do you think that supports?

MR. SIRI: Sure. So when you look at this clinical trial, clinical trials in order to be -- and I was going to do this through the witness, but clinical trials in order to be -- they need to usually have a few elements. One, they typically have a control group.

MR. LEUNG: Just summarize what those 200 plus pages say. You don't have to testify as to what -- what does it say?

MR. SIRI: What is shows is that there are only 800 or so participants in the clinical trial that's under powered, so you cannot --

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MR. LEUNG: And therefore, the MMR vaccine is dangerous? Is that what your saying?

MR. SIRI: No. I didn't say that.

MR. LEUNG: Okay.

MR. SIRI: And they looked at safety for 42 days.

MR. LEUNG: Okay.

MR. SIRI: So you couldn't find out what the long term adverse results were? And they had no control group, so you couldn't properly compare what the difference is in getting the MMR and not getting the MMR was. So they were under powered and was not -- and was only at 42 days at safety review and --

MR. LEUNG: I'm going to ask you to get to the end, therefore.

MR. SIRI: And therefore -- the therefore, it's more evidence towards the four points and I'm building the case right now, your Honor.

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MR. LEUNG: But I don't understand. Does that support the --

MR. SIRI: What it shows is that -- what it shows is that the four was licensed. It shows two things. One, you didn't know what the long term adverse reactions to this product was before it was licensed.

MR. LEUNG: Okay.

MR. SIRI: One undisputable. I don't think she would dispute, if I could ask her, because it's safe. Two, when you look at the actual -- it was eight little clinical trials and it has the adverse reactions. So I would like to submit those. So this is a summary of just taking out --

MR. LEUNG: This is a -- how many pages would you say this is here?

MR. SIRI: I don't know. 25.

MR. LEUNG: Mark this as P-4.

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MR. SIRI: This is just the relevant --

MR. MERRILL: This is part of three?

MR. LEUNG: This is all part of that. Okay. I'm sorry.

MR. SIRI: This is part of three, that's right. I wanted to --

MR. MERRILL: I think this is irrelevant.

MR. SIRI: Its irrelevant parts.

MR. LEUNG: I'm going to mark this as P-4 and P-5.

Any objections?

MR. MERRILL: I haven't seen it, but --

MR. SIRI: For completeness, I'm just fine with withdrawing this, if you just want that. That's just the relevant part.

MR. LEUNG: No. Its okay. I will take everything you have, but I would like you to summarize what this

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is. Tell me.

MR. SIRI: Let me get the document here. Take a copy, please. So now, if you look at -- so this is what the -- go to the third page 3. Okay. On the third page this is a summary.

MR. LEUNG: Are you following along? Do you have this?

MR. MERRILL: No, your Honor.

MR. SIRI: Do you have a copy? Here you go (handing).

MR. LEUNG: This is Petitioner's 4. And Petitioner's 4 is the Department of Health and Education and Welfare, date stamped September 15, 1978. Go ahead.

MR. SIRI: Okay. Let me get the FOIL request. I just want to make sure nobody -- this is the clinical trial that licensed this product by the FDA. If there is any objection to that, I also have the FOIL response.

1
2 MR. LEUNG: Counsel, there is
3 no objection.

4 What I want you to do is just
5 get the summary of what it is.

6 MR. SIRI: Third page. If you
7 go to the third page you can see that
8 it's the summary of the clinical
9 trials. Okay. And you can see there
10 are one, two, three, four, five, six,
11 seven --- there are eight.

12 Basically, there are eight studies
13 and you see the total participants is
14 834 individuals.

15 Do you see that?

16 MR. LEUNG: I do.

17 MR. SIRI: Okay. So that's the
18 total number of individuals that
19 received MMR to license this product.
20 Okay. And if you look at the
21 Summary, there is no control group
22 that was used. There's no placebo
23 control group. So they weren't
24 comparing it to anything.

25 Please turn to the next page

1
2 and let's look at the adverse
3 reactions from the MMR vaccines in
4 this trial. Please turn now to upper
5 respiratory illness.

6 Do you see that?

7 MR. LEUNG: Yes.

8 MR. SIRI: Okay. Do you see in
9 zero to four days? 60 --
10 39.6 percent of the children in the
11 trial had an upper respiratory
12 illness after getting MMR between
13 five and 12 days. 38.5 percent,
14 those are very significant numbers of
15 children that had respiratory illness
16 in this trial. If you go down and
17 look at gastrointestinal illness.
18 Similarly you can see the number of
19 children that had gastrointestinal
20 illness following the MMR vaccine.
21 One of the things that their
22 complaining about in the order is
23 that the measles can cause pneumonia
24 and diarrhea.

25 MR. LEUNG: Mr. Siri, can I

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stop you there?

MR. SIRI: Yeah.

MR. LEUNG: Does the child in question have any of these adverse reactions?

MR. SIRI: He hadn't received the MMR vaccine, your Honor.

MR. LEUNG: Okay.

MR. SIRI: Okay. So how can he? He hasn't received it yet.

MR. LEUNG: Okay.

MR. SIRI: He could.

MR. LEUNG: Does he have a doctor who can testify --

MR. SIRI: There's a doctor right here, your Honor.

MR. LEUNG: No. No. No. Does the child have a doctor that can attest to the fact that this child taking this vaccine will be detrimental to his health?

MR. SIRI: There's an obligation for him to go do that.

MR. LEUNG: Well, I'm trying --

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MR. SIRI: I mean --

MR. LEUNG: There's an
obligation in the sense that --

MR. SIRI: There's a --

MR. LEUNG: There's an
obligation in the sense that your
trying the summons alleging a failure
to immunize. And the defense, the
allegations says that he wasn't
immunized as required by law. Didn't
have proper test showing that he had
proper immunity or any document
showing that there was a proper
exemption.

MR. SIRI: Yeah. I'm showing
that it's not medically appropriate
to give this child -- when you look
at the clinic trials, when you look
at the post-licensure, safety studies
conducted by the CDC.

MR. LEUNG: So your saying that
the summons should not -- this is an
argument in cubby hole -- that it
should not have been issued?

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MR. SIRI: I'm saying that even the summons on its face says it should not be medically appropriate. Your saying -- adding the requirement that a doctor issue it. I don't know why that's required --

MR. LEUNG: Okay.

MR. SIRI: -- all of a sudden.

MR. LEUNG: So your saying it's not medically -- so your saying that it supports the idea?

MR. SIRI: The four buckets.

MR. LEUNG: Okay.

MR. SIRI: It's unjust, the risk outweigh the benefits, it's not medically appropriate. Right. You know that part.

MR. LEUNG: I have it.

MR. SIRI: You have it.

MR. LEUNG: Anything else?

MR. SIRI: You will continue -- if you go through it, you will see all of that for all of these. Okay.

MR. LEUNG: Okay. Anything

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else in terms of that document?

MR. SIRI: Well, here's the thing, I'd like it to be accepted that, you know, I made a representation, but it's just counsel saying it. The doctor would have said it. What is a properly powered study, what is a placebo control, but I didn't have a chance to do that. So I'm going to leave it then. Obviously, she shouldn't now have a chance to now go and say stuff afterwards, after the fact, now that she's given a preview of the argument. She should have had an opportunity to say it beforehand when she would have, you know, not given a preview of the arguments, when truth was original to her. It's no longer original to her.

MR. LEUNG: I'm hearing arguments and testimony --

MR. SIRI: Because we're not there yet. Now, when the 1986 Act

1
2 was passed -- I'm going to read two
3 sentences from two provisions of law
4 into the record. Okay. One is the
5 1980 -- the national childhood
6 vaccine was codified at 42USC300AA 1
7 through 34. I'm going to read you
8 one sentence from that Act.

9 It says, "No person may bring a civil
10 action for damages in the amount
11 greater than \$1,000 or an unspecified
12 amount against a vaccine
13 administrator or manufacturer in a
14 state of federal court for damages
15 arising from a vaccine related
16 injury. That was in 1986. The
17 reason that was passed was because of
18 all the harm being caused with
19 vaccines at that time. There was
20 only one manufacturer left -- MMR,
21 DTaP, and Polio.

22 Those were the only three vaccines at
23 the time. They were going bust. The
24 U.S. Supreme Court said, the amount
25 of damages -- the amount of liability

1
2 was 200 times the amount of revenue
3 from the DTaP vaccine at that time
4 and MMR was having similar problems.
5 So instead of letting them make a
6 better safer vaccine, what Congress
7 did, was that they gave them immunity
8 from liability for their injuries.
9 Okay.

10 And the U.S. Supreme Court then said
11 -- just so you know, reading one
12 sentence. "We hold that the national
13 childhood and vaccine preempts all
14 design claims against vaccine
15 manufacturers. Both by plaintiff who
16 seek compensation for injury, death
17 cause of vaccine side effects." And
18 so, that is what the 1986 Act did.

19 And what it did is it removed
20 the market forces that drive action
21 seeking. Instead it made health
22 departments responsible for vaccine
23 safety. They sit and not choose --
24 actually, the Federal Health
25 Authority -- the CDC does. Now,

1
2 after the nineteen -- when the 1986
3 Act was passed, one of the things it
4 did, it actually told HHS, you need
5 to look at whether some of these
6 vaccines cause certain injuries.

7 HHS then in turn went and hired the
8 Institute of Medicine to conduct that
9 review. Okay. In that review -- can
10 I get the Exhibit 39, please?

11 The IOM issued its first report in
12 1991. All right. In that report it
13 looked at four commonly claimed
14 serious injuries from the Rubella
15 component of this vaccine. Okay.
16 And what it found was that, two of
17 those common reported conditions are
18 caused by the vaccine. All right.
19 The Rubella component of the vaccine.
20 One of those, okay --

21 MR. LEUNG: I'm going to mark
22 this was Respondent's 5, The Adverse
23 Effects of the Rubella Vaccine and
24 Pertussis.

25 MR. SIRI: Pertussis.

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MR. LEUNG: Pertussis.

MR. SIRI: So if you turn to
the second to last page, please.

MR. LEUNG: Any objection to
R-5 being admitted?

MR. MERRILL: Sure.

MR. LEUNG: No objection.

MR. SIRI: It's the Institute
of Medicine, I mean -- so you go to
the second to last page, which you
can see this is the Summary of
Conclusions. Okay. So under the
Rubella vaccine, which is in here
RA273, made with human diploid cells.
Diploid cells from the body of fetal
tissue. It says, "Evidence
insufficient to indicate." So they
didn't -- so there was no evidence
one way or the other whether or not
it causes radionucleotide and other
neuropath -- neuropathies
thrombocytopenic purpura. Okay.
But it was -- evidence was consistent
with the causal or indicated the

1
2 causal with chronic arthritis and
3 acute arthritis. Okay. The next
4 report issued by the IOM was then in
5 1994. That's Exhibit 314. Okay.
6 And what the IOM this time looked at,
7 they looked at the Rubella component.
8 As you know, the MMR stands for
9 Measles Mumps, Rubella.
10 So they looked at the Rubella
11 component in the 1991 report. In the
12 1994 report, they looked at the
13 measles mumps and the measles
14 component. And what they did in that
15 report, they looked at the 22 most
16 commonly claimed serious adverse
17 reactions after that vaccine. And
18 what they found in that report is --

19 MR. LEUNG: Respondent's 6 is
20 what counsel is going to read from.
21 If there is any objection by the
22 Health Department, let me know.

23 MR. MERRILL: No.

24 MR. LEUNG: No objection. It's
25 admitted. Go ahead.

1
2 MR. SIRI: Okay. So if you go
3 to that one -- and if you go to the
4 fourth -- if you go to the fourth to
5 last page, this is the Summary of the
6 Causality Table. Okay. And so, here
7 they said, okay. These are the
8 conditions we know we believe are
9 caused by it. These are the ones
10 that we believe -- are the ones that
11 we believe are not caused by it and
12 these are the ones that we don't
13 know.

14 And what your going to find is, and
15 it's very troubling, is that for
16 eighteen of them, the IOM said you
17 didn't do the science. We don't
18 know. Even though they we're
19 commonly reported, we don't know
20 whether or not the measles or mumps
21 component cause encephalopathy, which
22 by the way, they later found out that
23 it did. That's brain damage, as you
24 know. Subacute scoliois or aseptic
25 meningitis and sterility or optic

1
2 neuritis. Right. Damages to the

3 nerves and the eyes. Right.

4 Do you see that under mumps -- under

5 measles and mumps on the fourth to

6 last page. Fourth to last page. Can

7 I lean over, your Honor to --

8 MR. LEUNG: Yep.

9 MR. SIRI: I'm going to help

10 you out there. Is that okay? I

11 don't want to get in your space too

12 much.

13 So here's the measles and the mumps,

14 a Category 1, is no evidence bearing.

15 Category 2, the evidence inadequate

16 to accept or reject. And you can see

17 under measles and mumps, the science

18 wasn't conducted to figure out were

19 these things or were they not caused

20 by the measles and the mumps.

21 MR. LEUNG: Okay.

22 MR. SIRI: Okay.

23 THE COURT: Gotcha.

24 MR. SIRI: Now, if you go to

25 the next page, you can also see the

1
2 evidence favors rejection. So far
3 there is nothing that was rejected
4 and the favor did accept causation
5 for anaphylaxis for the measles
6 vaccine.

7 MR. LEUNG: Okay. What else do
8 you have here?

9 MR. SIRI: Okay. And then
10 there's another page that was also
11 accepted for thrombocytopenia, as
12 well as, death. Death can result
13 from the measles vaccine, according
14 to the Institute of Medicine. Okay.
15 Now, what the IOM said in this report
16 was -- reading one sentence. "The
17 lack of adequate data regarding many
18 of the adverse events under study was
19 a major concern to the committee."
20 They said, Hey, HHS. Do your job.
21 You got to do studies to find out.
22 Does this vaccine -- does it or does
23 it not cause it? But you know what
24 HHS answer is. HHS also responded to
25 Vaccine Court, if it does any study

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that shows that the vaccine causes harm, what will happen is that it will be used against it in Vaccine Court. So under the 1986 Act, you can sue for a vaccine injury, but the Respondent is the Department of Health and Human Services.

MR. LEUNG: Mr. Siri --

MR. SIRI: I'm moving on.

MR. LEUNG: Before we move on. How many documents do you have approximately?

MR. SIRI: I don't know.

MR. LEUNG: Just give me an approximate.

MR. SIRI: Maybe a dozen, two.

MR. LEUNG: Okay. I'm going to ask --

MR. SIRI: I'm going to go quickly.

MR. LEUNG: No. I'm going to ask you to mark them from R-7 -- mark them all R-7 upwards. And then I'm going to ask you to give them to me

1
2 in mass and I'm going to ask you to
3 read the title of it. And I'm going
4 to -- what I don't want you to do is
5 right now -- I'm allowing you to make
6 a record.

7 MR. SIRI: 43.

8 MR. LEUNG: But I'm going to
9 make my determination. And my
10 instinct right now, is that this is
11 not relevant to the three issues of
12 whether or not the child was
13 vaccinated, whether or not he had
14 tested immunity, and whether or not
15 there was a medical exemption. So
16 I'm going to ask you to mark them, if
17 you can. R-7 -- Starting with R-7.

18 MR. SIRI: Sure. R-7. So this
19 is a report from 2012. This looked
20 at 31 commonly claimed injuries from
21 the MMR. And R-7 --

22 MR. LEUNG: Yes.

23 MR. SIRI: And this one found
24 that a significant amount of them
25 were caused by the MMR, but 23 of

1
2 them they have no idea. Again, IOM
3 said, Hey, why aren't you doing the
4 science that's needed? Exhibit 48.

5 MR. LEUNG: Is your copy --

6 MR. SIRI: Wait a second. Wait
7 a second. I'm sorry. Is that 43?

8 Let me get 48. So R-8 -- so the R-8

9 is an excerpt from the 1994 IOM

10 Report in which it says, "The

11 Committee was able to identify little

12 information pertaining to why most

13 individuals reacted adversely to

14 vaccines when most do not." Okay.

15 And so, what it did was say, Hey, you

16 got to do the studies for which

17 children are going to be susceptible

18 to injury.

19 Okay. And this is or -- this is

20 Exhibit 49. And so, this is, you

21 know, 2012, over a dozen years later.

22 The IOM, again, looked at this issue

23 and it said, both epidemiological

24 mechanistic research suggest the most

25 individuals who experience an adverse

1
2 reaction of a preexisting
3 susceptibility -- these
4 predispositions can exist for a
5 number of reasons. Genetic variance,
6 okay. Environmental exposures,
7 behavior, renal illness,
8 environmental stages. All of which
9 can interact to suggest some of these
10 are specific to the particular
11 vaccine, while others may not be.
12 Some of these predispositions maybe
13 detectible prior to administration of
14 vaccines. Much more work remains to
15 be elucidate and to develop
16 strategies to document genealogical
17 mechanisms that lead to adverse
18 affects in individual patients. What
19 they're saying is, vaccines, MMR can
20 cause -- we can't identify which
21 children will be injured, but you
22 haven't done the science to figure
23 that out. Let me get Exhibit 225.
24 Okay. I would like to ask -- I would
25 like to ask whether or not they know

1
2 the child? If the child is pre
3 genetic predisposition, that would
4 render them susceptible to an adverse
5 action of MMR. But I see where your
6 rejection stands because, for
7 example, here is -- here is a study
8 that identifies specific genetic
9 markers for when a child will have a
10 seizure -- will have seizures after
11 the MMR vaccine.

12 This is conducted by a reputable
13 purviewed science mainstream journal
14 by institutions.

15 MR. LEUNG: Counsel, I
16 appreciate you commenting.

17 MR. SIRI: Yep.

18 MR. LEUNG: But move along.

19 MR. SIRI: So this is -- what
20 is this R-10?

21 MR. LEUNG: I've given you an
22 opportunity to submit the evidence
23 and to comment on what it says.

24 MR. SIRI: I mean, I'm doing it
25 in this fashion, your Honor. But my

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objection stands, that this is not --

MR. LEUNG: I understand your objection.

MR. SIRI: -- appropriate for me to make a proper record.

MR. LEUNG: I understand that. I'm trying to balance the needs of the tribunal, the opportunity to give you a full and fair hearing, and be respectful of the opportunity to expound as much as you can, but I have to use my discretion and limit it as much as I can.

MR. SIRI: Okay.

MR. LEUNG: Your going to move onto R-11, while I let you talk and tell me what this is.

MR. SIRI: So R-11 is -- this is an example of a compensation of \$100 million that was given by the Vaccine Corp for an injury after the MMR vaccine.

MR. LEUNG: Thank you. Can we move onto R-12.

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2 MR. SIRI: The next one
3 requires me to ask questions. It
4 regards antibodies and what
5 antibodies does in the body.

6 MR. LEUNG: Tell me what R-12
7 says first.

8 MR. SIRI: What I just gave
9 you?

10 MR. LEUNG: No. R-12, the
11 thing that's coming.

12 MR. SIRI: Not everything I
13 have has exhibits. I'm only giving
14 you exhibits that I have, but I have
15 a lot of -- these are just questions
16 to elicit evidence from the witness.
17 Most of what I was going to do today
18 regarding gaining evidence. In fact,
19 I would think that would be
20 advantageous for them because it is
21 their witness.

22 MR. LEUNG: No. What I'm doing
23 is, I'm allowing you to produce
24 whatever evidence you want. I'm
25 giving you a sentence to comment on

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what the evidence is.

MR. SIRI: Okay.

MR. LEUNG: And I'm admitting
it without objection. Okay. So I'm
giving you every opportunity to put
in hundreds of pages of documents.
So can we move onto R-12?

MR. SIRI: Sure.

MR. LEUNG: Move onto R-12.

MR. SIRI: So what this is,
this is an ingredient list for the
vaccine, which your going to find is
-- what's in this vial is -- the
virus has to grow on something.
Okay. And they have a growth medium
that they need to grow on so each
component -- so the measles, Mumps,
Rubella are either grown on the
embryo culture human diploid
fibroblast fetal bovine serum. And
actually most of what you have in
this vial is the actual growth medium
that it's grown on. So you have
components from chickens, from cows,

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as well as, human diploid lung fibroblast.

Those are from the cultured cell line of an aborted fetus. So they take an aborted fetus, they take the lung fibroblast, they culture it. It only -- so it dies after generation. And what they do is, they grow the Rubella virus on it.

This vial contains millions of -- millions of pieces of human DNA in it. All broken down below 500 base pairs. Part of the manufacturing process. The whole point of this vaccine is ordered to create antibodies.

If your injecting it into the body, not only with a viral component, but the antigens from the human bovine and chicken components in particular.

The human components, it has the ability to create some various adverse events relating to that.

MR. LEUNG: Understood. We're

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going to move onto R-15.

MR. SIRI: You have Exhibit 60?
So you'll see on the third page
there's MMR. So Exhibit 307 and
Exhibit 341 and 308, these all
document the use of the aborted fetal
tissue. And that it is -- and that
the -- and that the subculture are
still in this product that your
looking at right now --

MR. LEUNG: Okay.

MR. SIRI: -- that they want to
inject into my client's body. And
they --

MR. LEUNG: This is the
document --

MR. SIRI: This is the -- so
you can match up WI38 and MR15C5.
Those are the ingredients on the
exhibit. I don't know what it was
market, the ingredients list, but the
vaccine you can match up --

MR. LEUNG: I'm going to mark
this as 13.

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MR. SIRI: Okay. And then
Exhibit 341 says that --

MR. LEUNG: This is 13. And is
that 14 for me?

MR. SIRI: Exhibit 341?

MR. LEUNG: Yes.

MR. SIRI: And so, when -- you
know, when they first licensed this
vaccine, they didn't understand the
concept of insertion Genesis. That
that DNA below 500 base --

MR. LEUNG: Can I ask you
something?

MR. SIRI: Yes.

MR. LEUNG: And I'm going to
ask you with all due respect.
Without like in a professor type
thing, educating me, Just tell me in
summary what it says. I don't need
the background.

MR. SIRI: Right.

MR. LEUNG: Just tell me what
it purports to.

MR. SIRI: I'm trying my best.

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MR. LEUNG: For instance, R-15.

MR. SIRI: I'm trying my best.

MR. LEUNG: Or whatever you
just said.

MR. SIRI: I'm trying my best
to give you what your asking for.

MR. LEUNG: I understand.

MR. SIRI: Despite the fact
that it is missing critical pieces to
the connected tissue.

MR. LEUNG: I understand.

MR. SIRI: So I'm not sure what
your, you know --

MR. LEUNG: What does R-14 tell
me?

MR. SIRI: You know, so what --
so R-14 and R15, those are the
product descriptions for what's on
the ingredients list.

MR. LEUNG: That's all I need.

MR. SIRI: That's what I was
telling you.

MR. LEUNG: Thank you.

MR. SIRI: And then R-15 --

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MR. LEUNG: Then we have R-16.

MR. SIRI: Exhibit 341. I
don't know what -- R-15. Your up
to --

MR. LEUNG: This one that we
have, R-15.

MR. SIRI: Yeah. So that's,
you know, that's a history of the use
of the tissue. Can I get Exhibit 70,
please.

This was one of the studies. This
was done with, you know, 80 aborted
fetuses in order to create the
Rubella component. Where they take
the fetus and make them into three
centimeter cubes --

MR. LEUNG: I'm going to mark
-- that was R-16.

MR. SIRI: -- and they culture
it to see if it's good for vaccine
production. And then let me just
skip ahead here to Exhibit 321. And
so, Exhibit 321 is -- this is
somebody who worked for a major

1
2 genetics company in Silicone Valley.

3 And so, she's got a letter regarding

4 the use of fetal DNA in the MMR

5 vaccine and issues related thereto.

6 Can I get Exhibit 267? Now, you

7 know, measles have been around since

8 the beginning of reporting history as

9 I understand. It's something that's

10 actually part of nature. God,

11 whatever one wants to call it. Okay.

12 But the MMR is not -- The MMR is a

13 manmade product. Okay.

14 It's something that only comes about

15 because of man's creation. And so,

16 you know, there might have been a

17 reason that the measles vaccine is

18 part of the natural world as we know

19 it. What this is, is handing you a

20 prospect study of 100,000 individuals

21 in Japan that were followed for

22 22 years by the Major Health

23 Authority. And what they found is,

24 that those that had gotten measles

25 and mumps -- okay.

1
2 Those that got measles and mumps,
3 95 percent of them were still alive.
4 They didn't die from cardio vascular
5 disease after 22 years. But of those
6 that didn't have measles and mumps,
7 okay, only 85 percent of them
8 survived. That's a huge
9 differential. And that is from major
10 purview study by major institutions.
11 What it shows is that getting measles
12 and mumps, potentially -- let me get
13 the next Exhibit 39. Getting measles
14 and mumps, the study indicates it
15 actually protects you from a cardio
16 vascular death. Cardio vascular
17 disease killed 6,000 Americans last
18 year. The measles killed 400
19 Americans a year in a few years
20 before the measles vaccine was first
21 licensed in 1963.
22 Okay. So if the measles -- in
23 eliminating measles cause five
24 percent of cardio vascular deaths.
25 That far outnumber the deaths from

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actual measles. You have 309? That is the -- that's the number of deaths from heart disease. And that study -- as far as that study remains un-rebutted in the medical literature, there's nothing that contradicts that finding.

MR. LEUNG: That's R-15 -- 19, counsel is referring to.

MR. SIRI: Yes. Now, there's also numerous -- numerous studies that show that those who had measles have far less rates of various cancers. Can I please have Exhibit 265? Okay. This is a study out of the International Agency for Research on Cancer in Leon France. Okay. And what they found, that those who had measles -- those who did not have measles had a 66 percent increased rate of Non-Hodgkin's lymphoma and a 233 percent increase rate of Hodgkin's lymphoma.

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MR. LEUNG: That's R-20.

MR. SIRI: That's R-20. And that one also remains un-rebutted in the medical literature, as far as we are aware. Can I get exhibits 310, 311, and 330. These are all studies constantly showing purview science, that those who have measles have far less rates of various cancer, including ovarian cancers. And Exhibit 335.

And I'm also going to provide you the number of people that died from Non-Hodgkin's lymphoma. That's 20,000 people last year. A percentage of that relates to people not getting measles. You can just do the math. 400 deaths for measles in the years before 1963, that's according to the CDC, verses how many people have died because you've eliminated measles and people who want to exercise their right not get this vaccine.

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MR. LEUNG: That's R-21.

MR. SIRI: Okay.

MR. LEUNG: Admitted.

MR. SIRI: Which one are you --

MR. LEUNG: Infectious
childhood diseases and history of
cancer patients and match control --

MR. SIRI: So one of those
actually was about ovarian cancer
kills 13,000 people a year in the
United States. It shows that having
measles having half the risk of
ovarian cancer.

MR. LEUNG: R-22 appears to be
a --

MR. SIRI: I just want to be
very clear for the record.

MR. LEUNG: Go ahead.

MR. SIRI: I'm not testifying
today. I am telling you these are
documents, and you know, the evidence
testifies.

MR. LEUNG: Exactly.

MR. SIRI: So these documents

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 speak -- meaning that I'm trying to fill in the gaps for you. I'm not a witness. I was intending to create the connective tissue with their own witness, but I am not --

 MR. LEUNG: Well, let me just say something. These are both hearings and attorney statements. When you come in, it is testimony to the extent that your introducing these documents. And you can testify in place of your client.

 MR. SIRI: Okay.

 MR. LEUNG: You can testify in place of the client's doctor. You can testify -- triple hearsay is permitted. Whatever you need to say, I'm taking into consideration. Everything is testimony. Okay.

 MR. SIRI: Triple hearsay.

 MR. LEUNG: Triple hearsay.

 MR. SIRI: What about quadruple?

 MR. LEUNG: Everything. Very

1
2 informal. R-23 is admitted. R-24 is
3 admitted. Everything from R-7 upward
4 that we have admitted. We're now up
5 to R-24 been admitted without
6 objection.

7 MR. SIRI: Let me just confirm
8 that we did -- we did all of these.
9 This is -- your being handed a survey
10 from the Department of Healthcare and
11 Technology University of British
12 Columbia. Again, documenting
13 differentials --

14 MR. LEUNG: R-25 is admitted.

15 MR. SIRI: -- between those who
16 have had measles and those who have
17 not had measles.

18 MR. LEUNG: Is this the last of
19 the documents, counsel?

20 MR. SIRI: Nope. 312 is --
21 that gives you the number of deaths
22 from ovarian cancer per year. So you
23 can have a comparative study. There
24 are various -- I don't know how to do
25 this? But basically the doctor can

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explain this, but we're not going to do that. Essentially, the bottom line is -- I'll just leave it alone. Let me get --

MR. LEUNG: R-26 is admitted.

MR. SIRI: -- 329. These three. Okay. So these are studies that show that children who have had measles have far less allergies and atopic diseases. Atopic diseases are things like, asthma. It's when you're sensitized to something in the environment. So children that have had that have had measles have far less --

MR. LEUNG: That's R-27. It's admitted.

MR. SIRI: -- of these conditions. There are three of those. 329, 336, and -- 329 and 336. Just do those two. We don't need to use the other one. Two is enough. And then Exhibit 331. 331 is a study that also looked at

1
2 the Parkinson rate in adulthood in
3 those who have had measles and those
4 who don't. Those who have had
5 measles half the rate of Parkinson's
6 disease.

7 MR. LEUNG: Okay.

8 MR. SIRI: You know, when you
9 look at the world, my clients believe
10 that God created the world. That
11 there is a divine creator. There
12 might have been a reason that God
13 created the world the way he did.
14 They want to exist in this world the
15 way God created it. I think all of
16 these purviewed science that -- I
17 don't know any studies. We're not
18 aware of any studies that rebut these
19 findings. Hence, this is the best
20 available evidence of what --

21 MR. LEUNG: R-29 is admitted.

22 MR. SIRI: -- supports that on
23 the four prongs that we talked about.
24 Fairness, justice, medically
25 appropriate -- is it medically

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appropriate to increase a child's risk of cancer, atopic disease, heart disease, in order to prevent them from having what's typically been considered a mild childhood illness.

MR. LEUNG: Is this the end of the documents?

MR. SIRI: Almost. So Exhibit 20 -- let me get Exhibit 20. So the Exhibit 20, is the package insert for MMR. The MMR vaccine itself. So this is from the manufacturer. You can see in there despite millions of pieces of DNA, its never been evaluated for whether it can mutate genes.

MR. LEUNG: Exhibit R-30 admitted.

MR. SIRI: Let me get Exhibit 313. This is a study out of Canada from their health authorities. And what they did is, that they tracked what happens within two weeks of getting MMR. How many kids went

1
2 to the emergency room that wouldn't
3 have otherwise went. One in 168
4 children ended up in the emergency
5 room, according to the Canada health
6 researchers, that wouldn't have
7 otherwise ended up there because they
8 received the MMR vaccines.

9 A pretty recent study. I'm still
10 waiting for an HHS response on that
11 one. It's quite a concerning
12 finding, but obviously that's, you
13 know, an issue in Vaccine Court.

14 Because you know, my firm does
15 vaccine injury cases.

16 And Vaccine Court, we have cases from
17 CDC or -- if it shows that the
18 vaccine causes harm, they're going to
19 be liable because they're the
20 Respondent in the vaccine injury
21 compensation program. It's part of
22 the Federal Court of Claims. You can
23 go to the Federal Court of Claims
24 website anytime. Click on vaccine
25 claim and you can read all about the

1
2 Vaccine Injury Compensation Program
3 down in Washington, D.C. That's
4 administered in the Federal Court of
5 Claims and specialized program, but
6 there's no discovery.

7 And you have to give all your
8 evidence and the Government is
9 defended by the law firm called the
10 Department of Justice. Just like
11 there are government attorneys here
12 defending vaccines. There are
13 government attorneys defending it on
14 the federal level too. Did we do
15 exhibit -- where are we at? Okay.
16 We did 313. Okay.

17 You know in Exhibit 20, just point
18 out, that it has a long list of
19 adverse reactions. I'm just going to
20 read 21CFR. It's one sentence.
21 201.57C7, and what the code of
22 federal regulations provides is that
23 on the package insert, despite
24 popular belief, the only adverse
25 reactions that are supposed to be

1
2 listed that are postmarketing are,
3 "Only those adverse events for which
4 there are some basis to believe that
5 there is a causal relationship
6 between the drug and the occurrence
7 of the adverse event."

8 That's the Code of Federal
9 Regulations. When you see adverse
10 events on the MMR package insert, the
11 only reason it's there is because the
12 manufacturer had a basis that they
13 are causally related, but they're not
14 liable. They pop it on there and
15 then who knows what their evidence is
16 because it can't be discovered.

17 MR. LEUNG: Are you done with
18 the documents, counsel?

19 MR. SIRI: 22 and 21. These
20 are examples of Merck amending their
21 package insert to add transverse
22 myelitis in 2014. And another, I
23 think, serious injury in 2017 -- of
24 course getting discovery as to the
25 evidence that's supported that you

1
2 can't get because you can't sue them
3 for the injuries. You can get, you
4 know, hundreds of millions of dollars
5 for robo violations, but you can't
6 get a dollar pretty much out of Merck
7 unless they commit fraud for if a
8 child dies from an MMR vaccine.
9 Let me get exhibit number 53. So
10 there's actually one study that I'm
11 aware of that looked at the health
12 outcome of children that are
13 vaccinated and unvaccinated children
14 in the United States. It was a small
15 study. It could be far better, but
16 it's the only one. It's Exhibit 53.
17 And what it found was, there's lots
18 of issues and concerns that the IOM
19 looked at that are on the package
20 insert. And that study found it was
21 out of the School of Public Health -
22 Jackson University, were increased.
23 You know, the question is one of, Are
24 you avoiding a limited infection for
25 a chronic health issue?

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MR. LEUNG: Counsel.

MR. SIRI: Okay. Moving on.

Moving on.

MR. LEUNG: Counsel, I'm going to ask you to document -- how many more do you have.

MR. SIRI: Seven --

MR. LEUNG: How many more do you have, approximately?

MR. SIRI: I've only got four more pages. So we went through -- we're on page 19. I got four more pages. So that much (indicating). Okay. Exhibit -- what's was the one that we just did? Exhibit 16?

MR. LEUNG: 34.

MR. SIRI: We just did 34? We're on 53.

MR. LEUNG: We just did this one (indicating).

MR. SIRI: We just did that. Oh, okay. So you know this is a report by the Congress with regard to, you know, ACIP that we talked

1
2 about earlier. ACIP makes the
3 vaccine recommendations, including
4 adding MMR. And what Congress found
5 is that, most of those people who
6 stood on that ACIP Board, have
7 conflicts with pharmaceutical
8 companies. You can read it. It's a
9 wonderful interesting read.

10 Exhibit 238, please. And what you
11 can find here is that the CDC vaccine
12 schedule from 2000, which is the same
13 year that this report was issued, it
14 was on the schedule at that point.

15 Can I get Exhibit 16 as well -- oh,
16 we already did 16. Okay. Let's move
17 onto to Exhibit 272. So, you know,
18 understanding that pharmaceutical
19 companies -- I think I'm done in like
20 five, 10 minutes total.

21 MR. LEUNG: What I'm going to
22 do, counsel, is -- I'm going to let
23 you introduce whatever document you
24 have and I'm going to let the title
25 of those documents --

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MR. SIRI: I'm going as fast as I can.

MR. LEUNG: No. No. No. You can summarize what's coming.

MR. SIRI: I am -- I'm not slowing this down.

MR. LEUNG: No. No.

MR. SIRI: The only slowing down what's happening is --

MR. LEUNG: Tell me the titles of the documents that's coming in.

MR. SIRI: Okay. This is exhibit -- this is the mandate for a safer child vaccine, which is apart of the 1986 Act codified in the United States Code. It's what under pins vaccines in this country. You can see the title right there. What it does is that it requires -- and you can see these are titles. It has a general rule. It has a task force. It has a report that is submitted every two years to Congress in which HHS documents how they made vaccines

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safer.

Okay. Exhibit 273, you might just leave this out. Don't refer to it as we go through the next two because it is going to be irrelevant.

Essentially, because vaccine manufacturers have immunity, have liability, this is what undermines the activity. HHS is assuring their safety. You can see it under Provision 1.

And so, every year HHS submits a report to Congress. This is a stipulation from Federal Court. And what you'll find is that these reports required by Section C, every year, have never been submitted a single time. This was a stipulated order in Federal showing that they actually do that. And that's a simple requirement. Just submit a report.

Exhibit 274, please. And then for the task force, if I recall under the

1
2 title. Okay. This is the task force
3 for -- this document right here --
4 The Task Force For Safer Childhood
5 Vaccines okay. This task force is
6 supposed to make recommendations on
7 how to make vaccines safer to the
8 Secretary of HHS. And this is a
9 response to a FOIL request. And
10 you'll see that task force was
11 dissolved in 1998.

12 It doesn't even exist. They're
13 not doing even the simplest request
14 to make sure that the MMR vaccine is
15 safe. Let me get Exhibit 318 and
16 319. Okay. This is a group of
17 physicians that have compiled a
18 summary of the risks of the MMR
19 vaccine and so forth. You know,
20 these are physicians. So they're
21 writing it from the perspective of
22 physicians.

23 MR. LEUNG: Counsel.

24 MR. SIRI: And those positions
25 are 319 and 318.

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MR. LEUNG: Counsel, I'm going to stop you right there. I'm going to stop you right there.

MR. SIRI: Yeah.

MR. LEUNG: Let me stop you.

MR. SIRI: Sure.

MR. LEUNG: Let me put on the record, we've been on the record --

MR. SIRI: Deal with 146 --

MR. LEUNG: Hold on, counsel. We've been on the record two hours and 40 minutes now. You have documents to tend to show that the -- we have admitted 39 documents consisting of probably over 600 pages. Counsel, stop.

MR. SIRI: Yep.

MR. LEUNG: Stop. Okay. To the extent that you have further documents to support your proposition that this summons should not have been issued and it was unjust to issue it, I'm going to allow you to admit that and mark it. The next one

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2 to be 40. And I'm going to let you
3 mark it and your assistant mark it
4 from 40 onward. When it's marked and
5 everything is ready to be admitted.
6 Let me know.

7 Right now we're going to --
8 I'm going to allow both sides to go
9 to the substance. Is there anything
10 that you want to argue in terms of
11 summations? Because I'm moving to
12 that right now. Is there anything
13 else after you present this exhibit?
14 Is there other testimony you want to
15 provide that's relevant to the issues
16 in the summons.

17 MR. SIRI: Yeah. Can I just
18 give direction as to what exhibits
19 are to be marked, please.

20 MR. LEUNG: Sure.

21 MR. SIRI: So I'm going to
22 circle the ones that are left to be
23 marked.

24 MR. LEUNG: Just hold it until
25 you're ready and then I'm going to

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read it in all mass. Thank you. The documents that have been admitted so far all the way up to Respondent's 39.

Department of Health, any objections? Any objections to those being admitted into evidence?

MR. MERRILL: No objections.

MR. LEUNG: Okay. They're admitted into evidence.

MR. SIRI: And so, you know, between 1900 and 1962 -- okay. When there was absolutely no measles --

MR. LEUNG: Counsel, I'm going to stop you because I understand --

MR. SIRI: You said summations.

MR. LEUNG: Yeah.

MR. SIRI: Summing.

MR. LEUNG: Your summing up?

MR. SIRI: Summing.

MR. LEUNG: Go ahead.

MR. SIRI: You told me to sum. I figure you were giving me three sentences.

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MR. MERRILL: Do I get to put a couple of things in?

MR. LEUNG: Sure. Before we do the sum up, I'm going to turn to Department of Health.

MR. MERRILL: Okay. First I just want to add one more document, your Honor. This is the frequently asked questions. It was also handed out and serves to all the Respondents, which gives instructions on how to submit medical proof. I also have a --

MR. LEUNG: This is a multipage document that I'm going to mark as P --

MR. MERRILL: I thought we were on two.

MR. LEUNG: Two. Okay. I'm going to mark it as P-3. It's a document entitled Frequently Asked Questions New York City Measles Vaccine Order Zip Code 11205, 11206 --

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MR. SIRI: Can I see a copy
when your done?

MR. LEUNG: -- 11211 and 11249.
I'm handing it to counsel to look at
(handing).
Any objection to that being admitted
into evidence?

MR. SIRI: My only objection is
that, I don't have an opportunity to
cross-examine the Department of
Health about it.

MR. LEUNG: You can ask them
questions about it. There are
representatives here. You have a
question about it?

MR. MERRILL: It actually came
up in the testimony that you already
have about this questionnaire, but --

MR. LEUNG: Okay. But do you
have any questions for the Department
of Health, counsel, on this document?

First off, you don't object P-3
being admitted into evidence?

MR. SIRI: My objection is what

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it was.

MR. LEUNG: Okay.

MR. SIRI: You know this document also says that the vaccine is safe. And I think it implies that the benefits outweigh the risks.

MR. LEUNG: Gotcha. I understand.

MR. SIRI: And --

MR. LEUNG: I'm going to take your testimony that you disagree with the assertions in it.

MR. SIRI: So can I ask about the substance of this document? There's lots of things in here.

MR. LEUNG: What do you mean by, asking about the substance? What are you talking about?

MR. SIRI: Well, you know, there's a lot of assertions in this document.

MR. LEUNG: You don't have to ask questions. You can rebut the assertions based upon your testimony.

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MR. SIRI: Yeah.

MR. LEUNG: You can say,
paragraph 3, I disagree with it.

MR. SIRI: Okay. So for
example, the Health Department has
found multi-strategies to end the
outbreak. Now, what they did is in
the Jewish community when there were
cases, they excluded the children
from school. Okay. And they did
that back in 2018. Okay. By using
that heavy handed approach, for
months there were not that many
cases.

What they did is, they left
those people who have that firm
belief with injecting this product
with only two options. They either
had to give a product that was
against their conscious to do in the
way think lived for thousand years or
they had to give their child measles
to go back to school.

MR. LEUNG: Counsel, I think

1
2 this is in support of your summation
3 that this should not have been
4 issued. So I'm just asking --

5 MR. SIRI: Well, it's directed
6 really to what's being argued here.
7 Because it says in here -- it says,
8 you know, they tried. And so, what
9 they're -- I mean, I would do this
10 through -- you said I should just
11 summarize it. So the point is that,
12 what it did is that this wasn't an
13 outbreak in the traditional sense
14 epidemiologically. It didn't follow
15 that trend.

16 What it was that it became a key
17 component. Is that they had measles
18 parties as the Commissioner of Health
19 had said. Measles parties, that's
20 why it didn't go outside of the
21 Jewish community. People were trying
22 to get their kids back in school and
23 it was the heavy hand in the Jewish
24 community that did this. There were
25 cases in public schools where it

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didn't exclude the unvaccinated kids
in those schools.

MR. LEUNG: So P-3 --

MR. SIRI: I have more -- okay.

MR. LEUNG: So P-3 is admitted.

MR. MERRILL: There was a lot
of testimony earlier about -- were
people told that they could submit
medical objections and proof of
immunity and that's why --

MR. LEUNG: Was P-3 provided to
Respondent?

MR. MERRILL: Yes.

MR. LEUNG: Okay.

MR. SIRI: With the violation.

MR. MERRILL: I also want to
mark -- correct. I also want to
mark, and there's been a lot of
statutes and other things submitted,
but I want to submit a copy of Judge
McHale's (phonetic) decision, which
upheld the order back in April. So I
have a copy for you, Aaron.

MR. SIRI: Thank you.

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MR. MERRILL: I also want to point out that the safety of the vaccine was brought in that case as well. And if you look at the decision where there's doctors testifying, doctors submitting affidavits, there's a plaintiff expert, they also cited that Judge McHale found -- cited that there is very little mainstream scientific evidence about the --

MR. SIRI: I submit for the record --

MR. LEUNG: Submitted as P-4. Do you have -- we have any objection to this decision being admitted?

MR. SIRI: Just the characterization of number one, it only addresses --

MR. MERRILL: I'm quoting from the --

MR. SIRI: It only addresses one of the constitutional arguments

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that I raised. Not the -- and --

MR. MERRILL: We accepted a lot of hearsay and a lot of studies about the -- I want to point out that the doctors that testified, that were brought in there --

MR. SIRI: Those doctors are not here today. I didn't bring them in my case. I brought evidence from the Institute of Medicine, the FDA, the CDC. So most --

MR. MERRILL: You put in letters.

MR. SIRI: So most of the evidence speaks for itself.

MR. LEUNG: Counsel.

MR. SIRI: Yeah.

MR. LEUNG: Let's --

MR. SIRI: I was responding to his --he cut me off. I was responding.

MR. MERRILL: You cut me off right now. I let you go for hours and put in letters and --

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MR. LEUNG: All right.

MR. MERRILL: And last thing,
your Honor, I just want to read from,
I think it's Respondent's 2, the CDC
Statement, that's in context, which
has been grossly distorted.

MR. LEUNG: Respondent's 2?

MR. MERRILL: Yes. It talks
about Section 4, page 2, the risk of
vaccine reaction. I just want to say
that in the documents that plaintiff
has put in --

MR. SIRI: Let the documents
speak for themselves.

MR. MERRILL: Getting in --
well, getting an MMR vaccine is much
safer than gets Measles, Mumps, or
Rubella disease. Then going down at
the bottom and it talks about the
risks and the severe allergic
reaction. We had a lot of testimony
about that. It says, any medication
that causes severe allergic reaction,
such reactions to vaccines is

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estimated to be one in one million
doses.

MR. SIRI: That is only for
anaphylactic. Not for brain damage.
Not for coma. Not for seizure.
That's not for any of those.

MR. LEUNG: Okay.

MR. SIRI: That's not what it
says. And severe --

MR. MERRILL: And rear means
one in a thousand.

MR. LEUNG: Understood.

Do you have any objection to
the Decision that's marked as P-4,
that being admitted into evidence?

MR. SIRI: I don't have an --
it's a Decision. I have no
objection.

MR. LEUNG: So you consider
it --

MR. SIRI: I just want to say.

MR. LEUNG: If it's in
evidence, I'll consider it.

Do you have any objection for

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me considering this in my decision.

MR. SIRI: Well, I have -- yes.
I object to it being considered in
any way. Anything that is fact --

MR. LEUNG: P-4 is admitted
into evidence and your going to --

MR. SIRI: I object to you
considering assertions in there as
factual.

MR. LEUNG: Gotcha.

MR. SIRI: It's a legal
decision.

MR. LEUNG: Okay. Understood.

MR. SIRI: The facts. It's not
an evidence. It is what I --

MR. LEUNG: Understood.

MR. SIRI: And the
characterization --

MR. LEUNG: Hold on one second
before you go further. Because I'm
going to give you an opportunity, I
promise you. I'm going to give you
an opportunity.

MR. SIRI: Okay.

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2 MR. LEUNG: But you spoke at
3 length and I want to give the
4 Department of Health, Mr. Merrill, an
5 opportunity to address all the issues
6 that they have.

7 Is there anything else that you
8 want to add?

9 MR. MERRILL: No.

10 MR. LEUNG: Now that that's
11 done, I'm going to ask, do you have
12 anything that you want to testify to?
13 Anything of substance that you want
14 to tell me?

15 MR. SIRI: About?

16 MR. LEUNG: About the case.
17 Why we're here.

18 MR. SIRI: Well, you know, are
19 we just going to rest on this record.

20 MR. LEUNG: No. We don't have
21 to rest.

22 MR. SIRI: Look --

23 MR. LEUNG: First of all --

24 MR. SIRI: Listen, the record
25 is -- well, let's get these in. You

1
2 know, I just -- I mean, I want to --
3 my summations is as to the four
4 arguments. The four core arguments.
5 I don't believe -- I mean, I just
6 stand on my objection about not, you
7 know, being able to make a fulsome
8 record. Separate from that, I'm
9 happy. You know, I think that the
10 arguments that were made on the first
11 points speak for themselves. I'm
12 happy to rest on the record here
13 today if Mr. Merrill is as well.

14 MR. LEUNG: Okay. So there's
15 nothing further either side wants to
16 address; is that correct?

17 MR. MERRILL: Correct.

18 MR. SIRI: As long as your
19 objection stands, then no.

20 MR. LEUNG: You mean your
21 objection. Right?

22 MR. SIRI: I apologize. Your
23 limited rulings that I objected to.

24 MR. LEUNG: Right. Okay. I
25 have enough to make a decision. I'm

1
2 going to take the case under
3 advisement and issue a written
4 decision that you will receive in
5 30 days. Hearing nothing further
6 from either parties, this hearing is
7 adjourned. The record should reflect
8 that the extensive arguments that
9 formed the basis --

10 MR. SIRI: Oh, wait. Did we
11 finish putting the rest in?

12 MR. LEUNG: I'm going to do it
13 right now.

14 MR. SIRI: Okay.

15 MR. LEUNG: The extensive
16 arguments made at the end of the
17 latter portion of this hearing
18 apprised to subsequent summons that
19 we were going to either hear today or
20 adjourn at a later date, if we run
21 out of time. Mr. Siri has indicated
22 that the substantive arguments that
23 have taken up the majority of the
24 three hour hearing, is common. Is a
25 common defense to the subsequent

1
2 summons that we're going to hear. So
3 to the extent that the subsequent
4 summons will refer to the record,
5 here it will be to save time so that
6 all the arguments that took up over
7 two hours will not have to repeated.
8 So this record will be joining the
9 other records. The record should
10 reflect that I also admitted the
11 following documents: We ended at
12 R-39. We have now gone to R-40,
13 R-41, R-42, R-43, R-44, and R-45. I
14 have given a chance to the Department
15 of Health to review that.

16 Any objection going up to R-45?

17 MR. MERRILL: No, your Honor.

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19 (Continued on next page to
20 include jurat.)
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MR. LEUNG: Hearing no objections, these are admitted into evidence. And hearing nothing further from either parties; is that correct.

MR. MERRILL: That's right.

MR. LEUNG: This hearing is concluded. Thank you.

(Whereupon the hearing was concluded.)

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DEPOSITION OF ERRATA SHEET

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my deposition taken in the above-captioned matter or the same has been read to me and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Subscribed and sworn to before me
this ____ day of _____ 20__.

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Exhibit E

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the "affected zip codes"); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine, unless such person or, for a child, such person's parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner's exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

Exhibit F

Summons Issued to
Plaintiff-Petitioner
Ascher Berkowitz

SUMMONS NUMBER: 30376-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control **BUREAU:** Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 **Phone:** 347-396-7998

RESPONDENT: ASCHER BERKOWITZ **ID NUMBER:** 50093815

ADDRESS: 95 SKILLMAN ST #4C BROOKLYN, NY 11205 **PHONE:**

DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:30 AM **BOROUGH:** Brooklyn

PLACE OF OCCURRENCE : 95 SKILLMAN ST #4C BROOKLYN, NY 11205

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 24, 2019 AT 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- | | | | | |
|---|--|--------------------------------|---|--|
| <input type="checkbox"/> Manhattan | <input type="checkbox"/> Staten Island | <input type="checkbox"/> Bronx | <input type="checkbox"/> Queens | <input checked="" type="checkbox"/> Brooklyn |
| 66 John Street | 350 St. Marks Place | 3030 Third Avenue | 31-00 47 th Avenue | 9 Bond Street |
| 10 th & 11 th Floor | Main Floor | Room 250 | 3 rd & 4 th Floor | 6 th & 7 th Floor |
| New York, NY 10038 | Staten Island, NY 10301 | Bronx, NY 10455 | Long Island City, NY 11435 | Brooklyn, NY 11201 |

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.B., who is at least six months old, lives at: 95 SKILLMAN ST #4C BROOKLYN, NY 11205, which is located in one of the affected zip codes listed in the Order. On June 4, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.B. has no record of measles immunization. Respondent has failed to vaccinate child Z.B. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Pooja Jani



06/04/2019

Print Name

Signature

ID

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Print Name

Signature

Title

Date:

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Placé, Main Floor, Staten Island, NY 10301

**Health**

Information on Measles and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30376-19L0

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption).

New Residents

If you or your child were not born in the city, your provider will need a copy of the immunization history to add to the Citywide Immunization Registry (CIR) record. You should contact your or your child's previous health care provider, or the last school you or your child attended, for your immunization records. The state where you previously lived may also have your records in its immunization registry.

If you moved to the city from elsewhere in New York State, the immunization record may already be in the CIR. You should contact your or your child's previous health care provider, the last school you or your child attended, the New York State Department of Health, or your local (county) health department for your immunization records.

All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8844 or email a copy of the record to measlesreview@health.nyc.gov.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.



Frequently Asked Questions: NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for "measles"
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, M.D.
Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and


WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the “affected zip codes”); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine , unless such person or, for a child, such person’s parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner’s exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

Summons Issued to
Plaintiff-Petitioner
Chava Biederman

SUMMONS NUMBER: 30244-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE
DIVISION: Disease Control BUREAU: Immunization
AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Chava Biederman ID NUMBER: 50091950
ADDRESS: 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206 PHONE:
DATE AND TIME OF OCCURRENCE: April 29, 2019, 12:35 PM BOROUGH: Brooklyn
PLACE OF OCCURRENCE: 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 19, 2019 AT: 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan * Staten Island Bronx Queens XX Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, B.B., who is at least six months old, lives at 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206, which is located in one of the affected zip codes listed in the Order. On April 29, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child B.B. has no record of measles immunization. Respondent has failed to vaccinate child B.B. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice. I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling Signature ID 04/30/2019 Date
Print Name Signature ID Date
I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons. Received by:

Summons Issued to
Plaintiff-Petitioner
Beila Englander

NYSCEF *Doc. No. 1910128*
 718,388-0904

SUMMONS NUMBER: 30212-19L0
ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE
 DIVISION: Disease Control BUREAU: Immunization
 AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Bella Englander **ID NUMBER:** 50092096
ADDRESS: 252 Keap Street APT# 4, Brooklyn NY 11211 **PHONE:** _____
DATE AND TIME OF OCCURRENCE: May 1, 2019, 11:30 AM **BOROUGH:** Brooklyn
PLACE OF OCCURRENCE: 252 Keap Street APT# 4, Brooklyn NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 12, 2019 AT: 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- | | | | | |
|---|--|--------------------------------|---|--|
| <input type="checkbox"/> Manhattan | <input type="checkbox"/> Staten Island | <input type="checkbox"/> Bronx | <input type="checkbox"/> Queens | <input checked="" type="checkbox"/> Brooklyn |
| 66 John Street | 350 St. Marks Place | 3030 Third Avenue | 31-00 47 th Avenue | 9 Bond Street |
| 10 th & 11 th Floor | Main Floor | Room 250 | 3 rd & 4 th Floor | 6 th & 7 th Floor |
| New York, NY 10038 | Staten Island, NY 10301 | Bronx, NY 10455 | Long Island City, NY 11435 | Brooklyn, NY 11201 |

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.
REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.E., who is at least six months old, lives at 252 Keap Street APT# 4, Brooklyn NY 11211, which is located in one of the affected zip codes listed in the Order. On May 1, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.E. has no record of measles immunization. Respondent has failed to vaccinate child Z.E. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling

05/02/2019

Print Name _____ **Signature** _____ **ID** _____ **Date** _____
 I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by: _____

Print Name _____ **Signature** _____ **Title** _____ **Date:** _____

Summons Issued to
Plaintiff-Petitioner
Israel Fishman

SUMMONS NUMBER: 30412-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control **BUREAU:** Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 **Phone:** 347-396-7998

RESPONDENT: ISRAEL FISHMAN

ID NUMBER: 50094215

ADDRESS: 140 Hewes St BROOKLYN, NY 11211

PHONE:

DATE AND TIME OF OCCURRENCE: June 12, 2019 AT 9:28 AM

BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 140 Hewes St BROOKLYN, NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 31, 2019 AT 10:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- | | | | | |
|---|--|--------------------------------|---|--|
| <input type="checkbox"/> Manhattan | <input type="checkbox"/> Staten Island | <input type="checkbox"/> Bronx | <input type="checkbox"/> Queens | <input checked="" type="checkbox"/> Brooklyn |
| 66 John Street | 350 St. Marks Place | 3030 Third Avenue | 31-00 47 th Avenue | 9 Bond Street |
| 10 th & 11 th Floor | Main Floor | Room 250 | 3 rd & 4 th Floor | 6 th & 7 th Floor |
| New York, NY 10038 | Staten Island, NY 10301 | Bronx, NY 10455 | Long Island City, NY 11435 | Brooklyn, NY 11201 |

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, A.F., who is at least six months old, lives at: 140 Hewes St BROOKLYN, NY 11211, which is located in one of the affected zip codes listed in the Order. On June 12, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child A.F. has no record of measles immunization. Respondent has failed to vaccinate child A.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Pooja Jani

Print Name



Signature

06/13/2019

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Print Name

Signature

Title

Date:



Health

Information on Measles and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30412-19L0

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption).

New Residents

If you or your child were not born in the city, your provider will need a copy of the immunization history to add to the Citywide Immunization Registry (CIR) record. You should contact your or your child's previous health care provider, or the last school you or your child attended, for your immunization records. The state where you previously lived may also have your records in its immunization registry.

If you moved to the city from elsewhere in New York State, the immunization record may already be in the CIR. You should contact your or your child's previous health care provider, the last school you or your child attended, the New York State Department of Health, or your local (county) health department for your immunization records.

All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8844 or email a copy of the record to measlesreview@health.nyc.gov.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.

Summons Issued to
Plaintiff-Petitioner
Judith Fried

SUMMONS NUMBER: 30304-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Judith Fried

ID NUMBER: 50092652

ADDRESS: 42 Walton Street APT# 3A, Brooklyn NY 11206

PHONE:

DATE AND TIME OF OCCURRENCE: May 10, 2019 AT 2:22 PM

BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 42 Walton Street APT# 3A, Brooklyn NY 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 3, 2019 AT 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

Manhattan

Staten Island

Bronx

Queens

Brooklyn

66 John Street

350 St. Marks Place

3030 Third Avenue 31-00 47th Avenue

9 Bond Street

10th & 11th Floor

Main Floor

Room 250

3rd & 4th Floor

6th & 7th Floor

New York, NY 10038

Staten Island, NY 10301

Bronx, NY 10455

Long Island City, NY 11435

Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, H.F., who is at least six months old, lives at: 42 Walton Street APT# 3A, Brooklyn NY 11206, which is located in one of the affected zip codes listed in the Order. On May 10, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child H.F. has no record of measles immunization. Respondent has failed to vaccinate child H.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Jane Bedell

Signature

ID

5/13/2019

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Print Name

Signature

Title

Date:

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

Summons Issued to
Plaintiff-Petitioner
Malka Friedman

SUMMONS NUMBER: 30378-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: MALKA FRIEDMAN ID NUMBER: 50093819

ADDRESS: 564 WYTHE AVE #8A BROOKLYN NY 11249 PHONE:

DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:36 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 564 WYTHE AVE #8A BROOKLYN NY 11249

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 24, 2019 AT 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan Staten Island Bronx Queens Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Y.F., who is at least six months old, lives at: 564 WYTHE AVE #8A BROOKLYN NY 11249, which is located in one of the affected zip codes listed in the Order. On June 4, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Y.F. has no record of measles immunization. Respondent has failed to vaccinate child Y.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Handwritten signature of Pooja Jani

Pooja Jani Signature ID Date 06/04/2019

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons. Received by:

Print Name Signature Title Date

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301



Information on Measles and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30378-19L0

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption).

New Residents

If you or your child were not born in the city, your provider will need a copy of the immunization history to add to the Citywide Immunization Registry (CIR) record. You should contact your or your child's previous health care provider, or the last school you or your child attended, for your immunization records. The state where you previously lived may also have your records in its immunization registry.

If you moved to the city from elsewhere in New York State, the immunization record may already be in the CIR. You should contact your or your child's previous health care provider, the last school you or your child attended, the New York State Department of Health, or your local (county) health department for your immunization records.

All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8844 or email a copy of the record to measlesreview@health.nyc.gov.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.



Frequently Asked Questions:

NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for "measles"
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Oxiris Barbot, M.D.

Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the "affected zip codes"); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine , unless such person or, for a child, such person's parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner's exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

Summons Issued to
Plaintiff-Petitioner
Chanie Fulop

SUMMONS NUMBER: 30328-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Chanie Fulop ID NUMBER: 50093122

ADDRESS: 115 Wallabout St, Brooklyn, NY, 11206 PHONE:

DATE AND TIME OF OCCURRENCE: May 22, 2019 AT 12:20 PM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 115 Wallabout St, Brooklyn, NY, 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 10, 2019 AT 11:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan Staten Island Bronx Queens XX Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC, Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Pooja Jani Signature ID 05/23/2019 Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by: Print Name Signature Title Date

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

**Health**

Information on Measles Exposure and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30328-19L0

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption). All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8851 or email a copy of the record to measlesdocuments@health.nyc.gov.

What if I have been advised to stay home because of measles exposure and cannot attend the hearing?

If you cannot attend the hearing because of measles exposure — or for any other reason — follow the directions on the summons to reschedule.

What should I do about the MMR vaccine after the period of time that I was advised to stay home?

Schedule an appointment with your medical provider so that you can get the MMR vaccine on the first business day you are able to leave your home. Immediately fax (347-396-8851) or email (measlesdocuments@health.nyc.gov) your medical records (signed and dated by a medical professional) to the Health Department.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.

Summons Issued to
Plaintiff-Petitioner
Rachel Guttman

SUMMONS NUMBER: 30420-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control **BUREAU:** Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 **Phone:** 347-396-7998

RESPONDENT: Rachel Guttman **ID NUMBER:** 50094292

ADDRESS: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205 **PHONE:**

DATE AND TIME OF OCCURRENCE: June 13, 2019 AT 1:19 PM **BOROUGH:** Brooklyn

PLACE OF OCCURRENCE : 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205

The respondent is summoned to appear and respond to the details of violation(s) stated below:

HEARING DATE: August 1, 2019 AT 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

Manhattan	Staten Island	Bronx	Queens	XX Brooklyn
66 John Street	350 St. Marks Place	3030 Third Avenue	31-00 47 th Avenue	9 Bond Street
10 th & 11 th Floor	Main Floor	Room 250	3 rd & 4 th Floor	6 th & 7 th Floor
New York, NY 10038	Staten Island, NY 10301	Bronx, NY 10455	Long Island City, NY 11435	Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019 the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, I.G., who is at least six months old, lives at: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205, which is located in one of the affected zip codes listed in the Order. On June 13, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child I.G. has no record of measles immunization. Respondent has failed to vaccinate child I.G. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice.

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Gerald Cohen _____ **06/14/2019**
Print Name **Signature** **ID** **Date**

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by: _____

Print Name **Signature** **Title** **Date:**

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301



Information on Measles Exposure and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30420-19L0

Measles exposure date: June 7, 2019

Start date when the individual exposed to measles no longer needs to stay home: July 7, 2019

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption). All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8851 or email a copy of the record to measlesdocuments@health.nyc.gov.

What if I have been advised to stay home because of measles exposure and cannot attend the hearing?

If you cannot attend the hearing because of measles exposure — or for any other reason — follow the directions on the summons to reschedule.

What should I do about the MMR vaccine after the period of time that I was advised to stay home?

Schedule an appointment with your medical provider so that you can get the MMR vaccine on the first business day you are able to leave your home. Immediately fax (347-396-8851) or email (measlesdocuments@health.nyc.gov) your medical records (signed and dated by a medical professional) to the Health Department.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.



Frequently Asked Questions:

NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for "measles"
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, M.D.
Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person "shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health."

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the “affected zip codes”); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine , unless such person or, for a child, such person’s parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner’s exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

SUMMONS NUMBER: 30422-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Rachel Guttman ID NUMBER: 50094292

ADDRESS: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205 PHONE:

DATE AND TIME OF OCCURRENCE: June 13, 2019 AT 1:38 PM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: August 1, 2019 AT 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan Staten Island Bronx Queens XX Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, E.G., who is at least six months old, lives at: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205, which is located in one of the affected zip codes listed in the Order. On June 13, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child E.G. has no record of measles immunization. Respondent has failed to vaccinate child E.G. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Gerald Cohen

06/14/2019

Print Name

Signature

ID

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Print Name

Signature

Title

Date:

Handwritten initials

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
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- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

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Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301


Health**Information on Measles Exposure and the Civil Summons**

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30422-19L0

Measles exposure date: June 7, 2019

Start date when the individual exposed to measles no longer needs to stay home: July 7, 2019

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption). All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8851 or email a copy of the record to measlesdocuments@health.nyc.gov.

What if I have been advised to stay home because of measles exposure and cannot attend the hearing?

If you cannot attend the hearing because of measles exposure — or for any other reason — follow the directions on the summons to reschedule.

What should I do about the MMR vaccine after the period of time that I was advised to stay home?

Schedule an appointment with your medical provider so that you can get the MMR vaccine on the first business day you are able to leave your home. Immediately fax (347-396-8851) or email (measlesdocuments@health.nyc.gov) your medical records (signed and dated by a medical professional) to the Health Department.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.



Frequently Asked Questions:

NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for "measles"
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Oxiris Barbot, M.D.

Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person "shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health."

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the “affected zip codes”); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine , unless such person or, for a child, such person’s parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner’s exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

Summons Issued to
Plaintiff-Petitioner
Simon Josef



**OFFICE OF THE SHERIFF
LAW ENFORCEMENT BUREAU
210 Joralemon Street - 9th Floor
Brooklyn, NY 11201**



**SIMON JOSEF
217 KEAP STREET
#4L
BROOKLYN, NY 11211**

Case # 19024911

Dear SIMON JOSEF,

Confidential documents issued out of court have been filed with this office. These document(s) concern you personally and are of great importance. Please come into our office between 8:30 a.m. and 7:00 p.m. (Monday thru Friday) so that we may discuss this matter. Please bring this letter along with photo identification.

Yours Truly,

Deputy Sheriff MEDE/ ZONE 1

**IF YOU RECEIVE THIS LETTER AFTER A DEPUTY SHERIFF HAS SERVED
THE DOCUMENT(S) PLEASE DISREGARD. IF YOU HAVE NOT BEEN SERVED
PLEASE CALL: (718) 488-3545**

OUR OFFICE ADDRESS:

**OFFICE OF THE SHERIFF
KINGS COUNTY LAW ENFORCEMENT BUREAU
Municipal Building
210 Joralemon Street - 9th Floor
Brooklyn, NY 11021**

SUMMONS NUMBER: 30373-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control **BUREAU:** Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 **Phone:** 347-396-7998

RESPONDENT: SIMON JOSEF **ID NUMBER:** 50093812

ADDRESS: 217 KEAP ST #4L BROOKLYN, NY 11211 **PHONE:**

DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:30 AM **BOROUGH:** Brooklyn

PLACE OF OCCURRENCE : 217 KEAP ST #4L BROOKLYN, NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 18, 2019 AT 11:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- | | | | | |
|---|--|--------------------------------|---|---|
| <input type="checkbox"/> Manhattan | <input type="checkbox"/> Staten Island | <input type="checkbox"/> Bronx | <input type="checkbox"/> Queens | XX Brooklyn |
| 66 John Street | 350 St. Marks Place | 3030 Third Avenue | 31-00 47 th Avenue | 9 Bond Street |
| 10 th & 11 th Floor | Main Floor | Room 250 | 3 rd & 4 th Floor | 6 th & 7 th Floor |
| New York, NY 10038 | Staten Island, NY 10301 | Bronx, NY 10455 | Long Island City, NY 11435 | Brooklyn, NY 11201 |

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.


WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, H.P.J., who is at least six months old, lives at: 217 KEAP ST #4L BROOKLYN, NY 11211, which is located in one of the affected zip codes listed in the Order. On June 4, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child H.P.J. has no record of measles immunization. Respondent has failed to vaccinate child H.P.J. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Pooja Jani _____  _____ **06/04/2019** _____
Print Name **Signature** **ID** **Date**

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by: _____
Print Name **Signature** **Title** **Date:**

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "**MUST APPEAR IN PERSON**," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- **Online:** To submit a defense online, visit www.nyc.gov/oath.
- **Phone:** To schedule a hearing by phone, call (212) 436-0817.
- **Mail:** To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301



Health

Information on Measles and the Civil Summons

This document provides information about measles exposure and the civil summons issued to you by the New York City Department of Health and Mental Hygiene related to the measles outbreak in Williamsburg, Brooklyn.

Summons Number: 30373-19L0

Why was I issued a summons?

The Health Department has issued a civil summons to you for failing to comply with the April 9, 2019 Order of the Commissioner regarding measles.

You have the right to a hearing at the New York City Office of Administrative Trials and Hearings (OATH) (Hearings Division). Follow the instructions that are attached to the summons.

How can I provide information to show that I, or my child, have been vaccinated, have immunity or have a medical exemption?

If you believe that you or your child have received the measles, mumps, and rubella (MMR) vaccine; have immunity to measles; or have a medical condition that prevents you from getting the MMR, you may submit medical records (these include vaccination records, serology report to prove immunity, or medical documentation for an exemption).

New Residents

If you or your child were not born in the city, your provider will need a copy of the immunization history to add to the Citywide Immunization Registry (CIR) record. You should contact your or your child's previous health care provider, or the last school you or your child attended, for your immunization records. The state where you previously lived may also have your records in its immunization registry.

If you moved to the city from elsewhere in New York State, the immunization record may already be in the CIR. You should contact your or your child's previous health care provider, the last school you or your child attended, the New York State Department of Health, or your local (county) health department for your immunization records.

All records submitted to the Health Department must be signed and dated by a medical professional. The Health Department will review the medical records and may withdraw the summons.

Submit the medical record to the Health Department. Fax it to 347-396-8844 or email a copy of the record to measlesreview@health.nyc.gov.

If your medical provider does not have MMR vaccine or if you need to find a vaccine clinic, call 311 or go to the Health Department website <https://www1.nyc.gov/site/doh/index.page>.

Where can I find information about the Order of the Commissioner, measles or the MMR vaccine?

Information about the Order of the Commissioner, measles and the MMR vaccine is on the NYC Health Department's website at nyc.gov/health. Or call 347-396-7998 to speak to someone at the Health Department.



Frequently Asked Questions:

NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for "measles"
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Oxiris Barbot, M.D.

Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person "shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health."

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the "affected zip codes"); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine, unless such person or, for a child, such person's parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner's exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further.

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

Summons Issued to
Plaintiff-Petitioner
Baila Klein (Hauer)

SUMMONS NUMBER: 30216-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control **BUREAU:** Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 **Phone:** 347-396-7998

RESPONDENT: Baila Hauer **ID NUMBER:** 50092097

ADDRESS: 201 HOOPER ST , Brooklyn NY 11211 **PHONE:** _____

DATE AND TIME OF OCCURRENCE: May 1, 2019, 11:35 AM **BOROUGH:** Brooklyn

PLACE OF OCCURRENCE: 201 HOOPER ST , Brooklyn NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 12, 2019 AT: 10:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- | | | | | |
|---|--|--------------------------------|---|--|
| <input type="checkbox"/> Manhattan | <input type="checkbox"/> Staten Island | <input type="checkbox"/> Bronx | <input type="checkbox"/> Queens | <input checked="" type="checkbox"/> Brooklyn |
| 66 John Street | 350 St. Marks Place | 3030 Third Avenue | 31-00 47 th Avenue | 9 Bond Street |
| 10 th & 11 th Floor | Main Floor | Room 250 | 3 rd & 4 th Floor | 6 th & 7 th Floor |
| New York, NY 10038 | Staten Island, NY 10301 | Bronx, NY 10455 | Long Island City, NY 11435 | Brooklyn, NY 11201 |

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.K., who is at least six months old, lives at 201 HOOPER ST, Brooklyn NY 11211, which is located in one of the affected zip codes listed in the Order. On May 1, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.K. has no record of measles immunization. Respondent has failed to vaccinate child Z.K. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling

05/02/2019

Print Name

Signature

ID

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by:

Print Name

Signature

Title

Date:

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

Summons Issued to
Plaintiff-Petitioner
Malky Roth-Tabak

SUMMONS NUMBER: 30198-1910

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Malky Tabak ID NUMBER: 50091595

ADDRESS: 585 Marcy Avenue APT# 2E, Brooklyn, 11206 PHONE: _____

DATE AND TIME OF OCCURRENCE: April 21, 2019, 09:00 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 585 Marcy Avenue APT# 2E, Brooklyn, 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 6, 2019 AT 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

Manhattan	Staten Island	Bronx	Queens	XX Brooklyn
66 John Street	350 St. Marks Place	3030 Third Avenue	31-00 47 th Avenue	9 Bond Street
10 th & 11 th Floor	Main Floor	Room 250	3 rd & 4 th Floor	6 th & 7 th Floor
New York, NY 10038	Staten Island, NY 10301	Bronx, NY 10455	Long Island City, NY 11435	Brooklyn, NY 11201

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WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, C.R., who is at least six months old, lives at: 585 Marcy Avenue APT# 2E, Brooklyn, 11206, which is located in one of the affected zip codes listed in the Order. On April 21, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child C.R. has no record of measles immunization. Respondent has failed to vaccinate child C.R. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Print Name Deborah Kaplan **Signature** *Deborah Kaplan* **ID** _____ **Date** 4/23/19

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by: _____

Exhibit G

OATH Appeal
Decision for
Plaintiff-Petitioner
Ascher Berkowitz



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30376-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30376-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 27, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019 the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and /or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent submitted a declaration from the child's mother that on June 4, 2019, the child was healing from an eye surgery, that the child had had a previous reaction to a vaccine, and that on the pediatrician's advice she decided to delay MMR vaccination until the child's eye was fully healed.⁶ The mother's declaration was admitted into evidence without objection. Respondent suggested that no doctor's note was provided because the pediatrician feared the consequences of writing anything that said the child should not get a vaccine.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of an emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order that was claimed on scientific, religious, and moral grounds.⁸ As to the mother's declaration, Petitioner argued that although the child may or may not have been recovering from eye surgery that prevented vaccination on June 4 or while the child healed, there was ample time for compliance prior to that date. Petitioner also noted that by State law pediatricians are required to give notes for medical exemptions for other purposes, such as for school exams,⁹ and advised the hearing officer that Petitioner recently withdrew a similar case after verifying that a physician had indicated that the child might have had an exemption.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ Petitioner cited 10 NYCRR § 66-1.3, which sets forth required immunizations for school admission.

In the decision, the hearing officer credited the allegations contained in the summons. He found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that those arguments were beyond the scope of the hearing. On the merits of the case, the hearing officer found that "Respondent did not meet its burden in showing a medical exemption because a doctor's note was not provided by Respondent" and he sustained the violation.

On appeal, Respondent repeats by incorporation, the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹⁰ In addition, Respondent argues that he did not have a full and fair hearing because he could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds.

Petitioner asserts that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the named ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3), found in 48 RCNY of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

¹⁰ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

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IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order that required parents or guardians of children older than six months to have their children vaccinated against measles within forty-eight hours of the Order being signed unless they could demonstrate that the children had immunity to the disease or should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. As the summons in this case was dated after April 17, 2019, Respondent argues that it must be dismissed because by that date the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child had not been vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in this record to show that Respondent offered any proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ As Respondent did not offer proof to contest any of the

¹¹ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹² *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). After admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement.)

¹³ *See also Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

essential facts establishing the violation, and the DOHMH physician, who had personal knowledge of the same vaccination records examined by the IO, was available to testify, there was no showing that the IO was needed. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

OATH Appeal
Decision for
Plaintiff-Petitioner
Chava Biederman



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30244-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 30, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30216-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on April 30, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on April 29, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent asserted that the summons incorrectly showed Respondent's apartment as being on the second floor of the building instead the third; Respondent argued that a charge that she was in violation at that time in that place was an impossibility as she was not in that place. Respondent did not deny receipt of the summons by mail.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons, and that the Resolution was by its terms effective immediately.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁷ In response to Respondent's assertion that the summons showed the wrong floor for Respondent's residence, Petitioner argued that for the purposes of this summons, the floor was not material to the violation, that the material element for violating the Order was that the apartment was in Brooklyn, as alleged.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. The hearing officer found that the floor number listed in the summons, even if incorrect, did not affect Respondent's right to notice of the violation or to receive a fair hearing. He found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. The hearing officer credited the testimony and allegations contained in the summons. He found that they supported a violation of the cited section and that Respondent failed to provide a defense to the allegations.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

On appeal, Respondent repeats the arguments raised in Docket No. 30198-19L0, relevant to this and other cases, regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds. Specifically, as to this case, Respondent argues that the summons must be dismissed because Respondent was not present and did not reside at the alleged place of occurrence at the time of the alleged violation, an apparent reference to the floor number indicated on the summons.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0 and those made at the hearing. Petitioner asserts that the hearing officer was correct in finding that the Commissioner's Order was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power asserted in the Order, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient. Specifically, as to this summons, Petitioner asserts that the hearing officer was correct in finding that Respondent received notice of the violation and a fair hearing even if there was a defect in the floor number on the summons. Petitioner notes that Respondent did not contest receipt of service by mail or that she resides in an affected ZIP code. Citing *TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017), Petitioner argues that absent any demonstrated prejudice, dismissal based on notice is not warranted. Petitioner also argues that the standard for service in an administrative proceeding was met: "whether the notice under all the circumstances was reasonably calculated to make the parties aware of the proceeding so that they have an opportunity to be heard."¹⁰

ISSUES ON APPEAL

The issues on appeal are (1) whether misidentifying the floor location of Respondent's apartment in the summons required that the summons be dismissed; (2) whether Petitioner had the authority to issue the summons on the date it was issued; (3) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

⁹ "MMR" stands for Measles, Mumps, Rubella.

¹⁰ See *Reda v. Dep't of Health*, 137 Misc.2d 61, 62-63 (Sup. Ct. N.Y. Co. 1987), aff'd, 143 A.D.2d 1073 (1st Dep't 1988)

produce the IO for cross-examination; and (4) whether Respondent established a defense to the charge.

APPLICABLE LAW

48 RCNY § 6-08(b)(1)(ii) provides in pertinent part as follows:

(ii) Alternatively, the summons may be served by mail deposited with the U.S. Postal Service, or other mailing service, to any such person at the address of the premises that is the subject of the summons or, as may be appropriate, at the residence or business address of:

(A) the alleged violator,

.

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the

nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

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48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer’s decision.

Petitioner is correct that the floor location of Respondent’s apartment was not material to the charge. As Petitioner established Respondent’s residence in one of the subject ZIP codes, and service by mail was not denied, the hearing officer properly did not dismiss the summons because of a possible error in the floor number.

The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months of age who was living in designated ZIP codes in Brooklyn and who was not vaccinated against measles should cause the child to be vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner’s records that took place on April 29, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner’s authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

¹¹ In this regard, the Tribunal also finds no merit to Respondent’s contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY S 6-08(c)(2), I part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal. The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007).

In view of the foregoing, the Tribunal finds that an error in the summons stating the wrong floor location for Respondent's apartment did not require dismissal of the summons, that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirement of 48 RCNY S 6-08(c).

¹² *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). (After admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement.)

¹³ *See Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (There is a limited due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden of producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test.)

OATH Appeal
Decision for
Plaintiff-Petitioner
Beila Englander



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
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Appeal No. 30212-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 29, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30212-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 2, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 1, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons states that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties stipulated that all the arguments made and evidence submitted in the previous hearing for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Petitioner

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

submitted an additional document consisting of a list of contraindications for the MMR vaccine.⁴ Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁵ and that the child was not vaccinated. As in the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁶ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued.⁷ Respondent argued again that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also referenced. In this hearing, Respondent added that the mother of this child has 10 other children, all up-to-date on vaccines; that she is waiting to provide the vaccination when the child is older because she “believes the child is not immunologically capable of handling this vaccine without having serious reactions.”

Petitioner’s arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH’s power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued this Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself was an order under HC § 3.05 for which notice was provided in the narrative of the summon. Petitioner further argued that the Resolution was by its terms effective immediately, and that publication had bearing only on the question of service. Petitioner’s previous submissions included “Frequently Asked Questions” regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ As to Respondent’s assertion that the child was not capable of handling immunization at this time, Petitioner stated that nothing to that effect was submitted to the Petitioner and noted that the child was over a year old.

In the decision, the hearing officer found that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order and the Board by its Resolution directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer rejected Respondent’s argument that the Order had expired when the summons was written,

⁴ “MMR” stands for Measles, Mumps, Rubella.

⁵ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁶ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁷ As this summons was written after the Resolution’s three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

finding that the BOH Resolution of April 17, 2019, had continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Order. The hearing officer found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. He credited the IO and the allegations contained in the summons and found that they support a violation of the cited section of the law. The hearing officer noted Respondent's assertion that the child's mother did not vaccinate the child because she thought the child was not physically able to accept the vaccination. However, he found that Respondent had failed to provide a defense to the allegations and he sustained the violation.

On appeal, Respondent repeats the arguments raised in the prior hearing relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles, and the specific argument in this case that service of the summons was not proper.⁹ In addition, Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the NYCC, found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution dated April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

⁹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order requiring that any person living, working or residing in those ZIP codes who had not received the MMR vaccine be vaccinated within forty-eight hours of the Order being signed, unless such person could demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement, and ordered that a parent or guardian of a child older than six months have the child vaccinated unless the parent or

guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019. The Order remained in effect at least until the BOH met on April 17, 2019.

Respondent argues that the summons must be dismissed because it was served after the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 1, 2019. That examination provided uncontroverted evidence that the child had never been vaccinated, and therefore was not vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish¹⁰. There is no evidence in this record to show that Respondent offered any proof of immunity or documentation that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable.¹¹ Respondent did not offer proof to contest any of the essential facts establishing the violation so as to shift the burden back to Petitioner, *see* 48 RCNY § 6-12(b) (the summons, if affirmed, "will be admitted as prima facie evidence of the facts stated therein), and, in any case, the DOHMH physician had personal knowledge of the same vaccination records examined by the IO and was available to testify.

As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹¹ *See Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Israel Fishman



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Appeal No. 30412-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30412-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed on June 13, 2019, that on June 12, 2019, she reviewed the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), and observed that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and /or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. Petitioner added that the subject child in this case was five years old. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and that Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent added three additional defenses: (1) that the parent asserted he never received the summons in the mail; however, Respondent acknowledged Petitioner's affidavit of service, which was taken into evidence without objection; (2) that the parent did not have the child vaccinated because an older sibling had had an adverse reaction to the MMR vaccination, including loss of hearing and delayed speech, as established by the parent's declaration taken into evidence without objection; and (3) that there was an objection on religious grounds.⁶

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Commissioner's Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself was an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ As to the new defenses raised in this hearing, Petitioner asserted that a parent's belief that a child's issues were related to a vaccination did not mean that they were, nor did it establish a medical exemption. Citing the national standard for recommendations for immunizations set by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC), the DOHMH physician testified that any reaction in a household member or family member was not a contra-indication and that the parent would have needed to submit documentation for a medical exemption.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician indicated that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

In the decision, the hearing officer sustained the violation, finding that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order, and the Board by its Resolution, directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer rejected Respondent's argument that the Order had expired when the summons was written, finding that the BOH, by its Resolution of April 17, 2019, had continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Order. The hearing officer found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. He credited Petitioner's affidavit of service and found that the summons was properly mailed to Respondent's address. He found that Respondent's evidence had not established a medical exemption for the child, and that Respondent had failed to provide a defense to the allegations.

On appeal, Respondent repeats the arguments raised in the hearing relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles, and the specific argument in this case that service of the summons was not proper.⁹ In addition, Respondent argues that he did not have a full and fair hearing because he could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the NYCC, found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution dated April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, which is that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that even if it is found that the Resolution was not in effect until completion of publication, the Resolution "is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order." Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

⁹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer’s ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

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IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent

or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

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48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within 48 hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 12, 2019. That examination provided uncontroverted evidence that the child had never been vaccinated, a fact that was admitted, and therefore was not vaccinated during the forty-eight hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in this record to show that Respondent offered proof of immunity or documentation,

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY S 6-08(c).

¹¹ *See DCA V. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

such as a doctor's note, that that vaccination was medically inappropriate specifically for this child. It was not error for the hearing officer to credit the DOHMH physician's position that an adverse reaction by a sibling did not establish a medical exemption for the subject child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹²See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Judith Fried



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
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Appeal No. 30304-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30304-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 13, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 10, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent asked that the summons be dismissed because it was served in person after 11:00 P.M., which Respondent argued was improper. In addition, Respondent argued that the measles vaccine was not licensed for children under 12 months of age, and submitted declarations that the child's sibling previously suffered from moderate to severe adverse vaccine reaction and that the parent has a religious objection to the vaccination.⁶ The declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was in violation of the Resolution, which itself constituted an order under HC § 3.05, for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ The DOHMH doctor testified that the Advisory Committee on Immunization Practices,⁹ which sets the national standards for vaccination, states that during an outbreak, MMR vaccine may be used for children ages six to eleven months and recommends vaccinating children in that age group prior to international travel.¹⁰ She testified that the Advisory Committee does not consider reactions in siblings to be a

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ In the audio record, these declarations are referred to as affidavits, but the record does not show that they were sworn to.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in an earlier hearing, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

¹⁰ "MMR" stands for Measles, Mumps, Rubella.

contraindication, and pointed out that the parent did not submit documentation of a medical exemption for the child. Petitioner's counsel also noted that the claim for religious exemption is not a legal defense.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. He credited the testimony of the DOHMH physician that an adverse reaction to the MMR vaccine suffered by a sibling is not a medical justification to withhold the vaccine, and that a medical exemption was not established because Respondent did not provide a doctor's note. He also found that a religious objection was not a valid defense to the charge. The hearing officer rejected Respondent's assertion that service was improper because it was made at 11:15 P.M. as Respondent could not cite any regulation or case law to support that argument. He credited the allegations contained in the summons and found that they support a violation of the cited section of law. He found that Respondent had failed to provide a defense and sustained the charge.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹¹ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which in this case would include Respondent's objections on religious grounds.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct in finding that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

¹¹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer’s ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

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IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order

being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn, and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 10, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹²

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹³ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically

¹² In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear I alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹³ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁴ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁴ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Malka Friedman



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Appeal No. 30378-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30378-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent submitted a declaration from the child's father that on June 4, 2019, the date the summons was issued, the child had a moderate, acute illness, and a second declaration that, based on witnessing "two vaccine injuries," he believed that the vaccination was against his religious belief because "[w]e are forbidden to take any drug or do anything that can cause us harm." The declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05 for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁷ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds. Petitioner argued that a religious objection was not a defense to the Order. Petitioner also noted that the subject child was five years old.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that those issues were beyond the scope of the hearing. The hearing officer found that without a doctor's note to support the "vague description" of the child's illness, Respondent had failed to prove a medical exemption on the date of issuance. In addition, he

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

found that Respondent's declaration of religious objection was not a valid defense. He credited Petitioner's allegations and found that the Respondent's evidence did not provide a defense.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

⁹ "MMR" stands for Measles, Mumps, Rubella.

and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.
IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer’s decision.

The hearing officer credited the allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer’s credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or

guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. Even if the child was ill on the day the summons was issued, the violation was established by the failure to vaccinate during the time specified in the Order. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

OATH Appeal
Decision for
Plaintiff-Petitioner
Chanie Fulop



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
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Appeal No. 30328-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30328-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 23, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 22, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, and in several earlier hearings, Respondent asserted that the vaccine was not licensed for children under one year of age, and in this hearing noted that although Petitioner follows a recommendation that the vaccine be given during a measles outbreak, such use is not mandated. Respondent submitted the parent's declaration of a religious objection to the vaccine.⁶ In addition, Respondent submitted a notarized statement that she did not receive the summons in the mail although she admitted that it was posted on the door. These declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁸ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds. The DOHMH doctor testified that the Advisory Committee on Immunization Practices,⁹ which sets the national standards for vaccination, recommends that the vaccine be given to children age six to twelve months in an outbreak setting and routinely prior to international travel. As to the argument for a religious exemption, Petitioner noted that a religious objection was not a defense

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ Respondent asserted that her religion did not permit putting foreign substances into the body and, in addition, that this vaccine derived from a non-kosher species.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in an earlier hearing, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

to the Order, and as to service of the summons, Petitioner provided a copy of the deputy sheriff's affidavit of mailing.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. He noted and credited the testimony of the DOHMH physician that in emergency/outbreak situations, an MMR vaccine is appropriate for a child between six and twelve months.¹⁰ He credited Petitioner's certificate of service and found that the summons was properly mailed to Respondent's address. In addition, he found that a religious objection was not a valid defense to the charge. The hearing officer found that the allegations in the summons supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹¹ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the

¹⁰ "MMR" stands for Measles, Mumps, Rubella.

¹¹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

hearing officer’s ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.
IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.
.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 22, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹²

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹³ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁴ Respondent did not offer proof to contest any of the

¹² In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹³ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹⁴ *See Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness,

essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Rachel Guttman



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Appeal No. 30422-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30422-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on June 14, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 13, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁷ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. The hearing officer found that the allegations in the summons supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time

⁹ "MMR" stands for Measles, Mumps, Rubella.

period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.
IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.
48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer’s decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer’s credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner’s

records that took place on June 13, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Simon Josef



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Appeal No. 30373-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30373-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent submitted a copy of the parent/guardian statement prepared in connection with his request to the State Education Department for religious exemption from immunization. The statement was taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was in violation of the Resolution, which itself constituted an order under HC § 3.05, for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁷ Petitioner asserted that a religious objection was not a defense to the Order. Petitioner also noted that the subject child was non years old.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. In addition, he found that a religious objection was not a valid defense to the charge. The hearing officer credited the allegations contained in the summons and found that they supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that he did not have a full and fair hearing because he

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct in finding that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the

⁹ "MMR" stands for Measles, Mumps, Rubella.

Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer’s decision.

The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer’s credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17,

2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear I alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Baila Klein (Hauer)



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Appeal No. 30216-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 30, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30216-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 2, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner the Department of Health and Mental Hygiene (DOHMH), May 1, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live and work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, a DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. Respondent also argued that the MMR vaccine was not licensed for children under one year of age.⁶ For this hearing, Respondent argued that the summons should be dismissed for defective service because it was not given to Respondent, but to her father at his apartment, located on a different floor from Respondent's in the same building. Respondent stated that the father told the officer that it was not Respondent's apartment and the officer replied, "I will give it to her." Two declarations made by Respondent were taken into evidence, one as to service of the summons and one stating that the child was less than one year old.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons. Petitioner argued that the Resolution was by its terms effective immediately.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ The DOHMH doctor stated that despite the licensure issue, the Advisory Committee on Immunization Practices,⁹ which sets the national standards, recommends that a dose of MMR vaccine be considered in an outbreak setting to children ages six to eleven months, and routinely to that age group prior to international travel. As to service of the summons, Petitioner stated that the summons was also mailed to Respondent.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in a hearing held earlier that day, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. The hearing officer rejected Respondent's contention that service of the summons was improper. He found that Respondent's father was a person of suitable age and discretion as provided in 48 RCNY § 6-08(b)(1)(H) and that the mailing of the summons to Respondent satisfied the service requirement of 48 RCNY § 6-08(b)(1)(ii). He credited the testimony of the DOHMH doctor that in emergency/outbreak situations, an MMR vaccine is appropriate for a child older than six months. He credited the affirmations of the IO and the allegations in the summons and found that Respondent had failed to provide a defense to the charge. The hearing officer found Respondent's Constitutional and scientific arguments to be beyond the scope of the hearing.

On appeal, Respondent repeats the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹⁰ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds. Specifically, as to this case, Respondent argues that the summons was not properly personally served on her but rather on "the tenant who lives on the first floor of [her] building."

In response, Petitioner asserts that service of the summons was proper. Petitioner repeats the arguments made at the hearing and asserts that the hearing officer correctly found that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether service of the summons was proper; (2) whether Petitioner had the authority to issue the summons on the date it was issued; (3) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (4) whether Respondent established a defense to the charge.

¹⁰ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

APPLICABLE LAW

48 RCNY § 6-08(b)(1)(ii) provides in pertinent part as follows:

(ii) Alternatively, the summons may be served by mail deposited with the U.S. Postal Service, or other mailing service, to any such person at the address of the premises that is the subject of the summons or, as may be appropriate, at the residence or business address of:

(A) the alleged violator,

.

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

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IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer’s decision.

Per 48 RCNY § 6-08(b)(1)(ii), service of a summons may be made by mail. As there was uncontroverted testimony and documentation that the summons was mailed to Respondent, the Tribunal finds that service was proper. The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer’s credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner’s records that took place on May 3, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner’s authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

¹¹ In this regard, the Tribunal also finds no merit to Respondent’s contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that service of the summons was proper, that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹² See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹³ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

OATH Appeal
Decision for
Plaintiff-Petitioner
Malky Roth-Tabak



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

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Appeal No. 30198-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 29, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30198-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed on April 23, 2019, that on April 21, 2019, she reviewed the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), and observed that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's personal knowledge. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

codes,⁴ and that the child was not vaccinated. Respondent argued that the Order had already expired on the date of the summons and that Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that she could not be charged with violating the Resolution because the summons was issued before the required three-day publication period was completed. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents offered by Respondent regarding the efficacy and safety of the vaccination in general were taken into the record.

Petitioner noted that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an Order, which would be effective until the next BOH meeting. Petitioner argued that despite minor differences in language, the Resolution issued at that meeting continued the requirement already in effect that people be vaccinated, that the Resolution was by its terms effective immediately, and that publication had bearing only on the question of service. Petitioner's submissions included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁶

In the decision, the hearing officer sustained the violation, finding that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order, and the Board by its Resolution, directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer noted that Respondent made a variety of Constitutional and scientific arguments and challenges to the validity, efficacy and safety of the MMR vaccine and to the fundamental fairness of the summons and Petitioner's authority to mandate vaccination.⁷ The hearing officer noted, as well, Petitioner's responses and the NYS Supreme Court decision denying injunctive relief from the Order. *See* footnote 5 below. The hearing officer found that the Constitutional and scientific arguments were beyond the scope of the hearing. He found that the BOH Resolution of April 17, 2019, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019, and he found that Respondent failed to provide a defense to the allegations.

⁴ The DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ *See* 2019 NY Slip Op 31047 (April 18, 2019).

⁷ "MMR" stands for Measles, Mumps, Rubella.

On appeal, Respondent repeats the arguments made in the hearing.⁸ In addition, Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the New York City Charter (NYCC), found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution of April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, which is that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the stated intent of the Resolution was to be effective immediately, i.e., on April 17, 2019, and that the question of whether the BOH has the power in a public health emergency to make a Resolution effective prior to completion of publication under NYC Administrative Code (Code) § 17-148 "is more in the jurisdiction of another tribunal." Petitioner further argues that even if it is found that the Resolution was not in effect until completion of publication, the Resolution "is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order." Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency.

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order requiring that any person living, working or residing in those ZIP codes who had not received the MMR vaccine be vaccinated within forty eight hours of the Order being signed, unless such person could demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement. The Order further ordered that the parent or guardian of any such child older than six months of age should cause such child to be vaccinated within that forty-eight hour period unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019; the Order remained in effect at least until the BOH met on April 17, 2019. As the summons in this case was dated after April 17, 2019, Respondent argues that it must be dismissed because by that date the Order had expired. That is not correct. The summons, which was issued on April 23, 2019, was based on an examination of Petitioner's records that took place on April 21, 2019; that examination provided uncontroverted evidence that the child was not vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to

comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child was subsequently vaccinated.

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, it was for Respondent to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.⁹ There is no evidence in this record to show that Respondent offered any proof of immunity or any documentation that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁰ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician had personal knowledge of the same vaccination records examined by the IO and was available to testify. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections raised are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

⁹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹⁰ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

Exhibit H

**NEW YORK CITY OFFICE OF
ADMINISTRATIVE TRIALS AND HEARINGS**

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL
Hygiene,

Petitioner,

-against-
Chava Biederman

Respondent.

Summons No. 30244-19L0

DECLARATION OF
CHAVA BIEDERMAN

I, Chava Biederman, under penalty of perjury, aver the following:

1. I was issued Summons Number 30244- 19L0 from the New York Department of Health and Mental Hygiene.
2. The Summons listed the "ADDRESS" as 104 Heyward Street, Apt. 2FL, Brooklyn, NY 11206.
3. The Summons listed the "PLACE OF OCCURRENCE" as 104 Heyward Street, Apt. 2FL, Brooklyn, NY 11206.
4. The Summons listed the "DATE AND TIME OF OCCURRENCE" as April 29, 2019 at 12:35 PM.
5. The Summons references my child, B.B.
6. On April 29, 2019, neither B.B nor I were residing at 104 Heyward Street, Apt. 2FL, Brooklyn, NY 11206.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Date: August 22, 2019



Chava Biederman

Exhibit I

ARTICLE

Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection

Helen Rosenlund, MSc^{a,b}, Anna Bergström, PhD^a, Johan S. Alm, MD, PhD^{c,d}, Jackie Swartz, MD^e, Annika Scheynius, MD, PhD^f, Marianne van Hage, MD, PhD^g, Kari Johansen, MD, PhD^h, Bert Brunekreef, PhD^{i,j}, Erika von Mutius, MD^k, Markus J. Ege, MD^k, Josef Riedler, MD^l, Charlotte Braun-Fahrländer, MD^m, Marco Waser, PhD^m, Göran Pershagen, MD, PhD^{a,n}, and the PARSIFAL Study Group

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The authors have indicated they have no financial relationships relevant to this article to disclose.

What's Known on This Subject

Measles infection may have an immunosuppressive effect and, therefore, might affect the development of allergy, but the scientific evidence is inconsistent. Furthermore, measles vaccine has been associated with the development of allergy in some, but not all, previous studies.

What This Study Adds

This study adds a methodologic aspect to the association between measles vaccination and/or measles infection and allergic disease and atopic sensitization. In this study, we took confounding from disease-related modification of exposure into account.

ABSTRACT

OBJECTIVE. Our aim was to investigate the role of measles vaccination and measles infection in the development of allergic disease and atopic sensitization.

METHODS. A total of 14 893 children were included from the cross-sectional, multi-center Prevention of Allergy–Risk Factors for Sensitization in Children Related to Farming and Anthroposophic Lifestyle study, conducted in 5 European countries (Austria, Germany, the Netherlands, Sweden, and Switzerland). The children were between 5 and 13 years of age and represented farm children, Steiner-school children, and 2 reference groups. Children attending Steiner schools often have an anthroposophic (holistic) lifestyle in which some immunizations are avoided or postponed. Parental questionnaires provided information on exposure and lifestyle factors as well as symptoms and diagnoses in the children. A sample of the children was invited for additional tests, and 4049 children provided a blood sample for immunoglobulin E analyses. Only children with complete information on measles vaccination and infection were included in the analyses (84%).

RESULTS. In the whole group of children, atopic sensitization was inversely associated with measles infection, and a similar tendency was seen for measles vaccination. To reduce risks of disease-related modification of exposure, children who reported symptoms of wheezing and/or eczema debuting during first year of life were excluded from some analyses. After this exclusion, inverse associations were observed between measles infection and “any allergic symptom” and “any diagnosis of allergy by a physician.” However, no associations were found between measles vaccination and allergic disease.

CONCLUSION. Our data suggest that measles infection may protect against allergic disease in children. *Pediatrics* 2009;123:771–778

www.pediatrics.org/cgi/doi/10.1542/peds.2008-0013

doi:10.1542/peds.2008-0013

Key Words

allergic disease, atopic sensitization, measles infection, measles vaccination, Steiner-school children, farm children

Abbreviations

CI—confidence interval
IgE—immunoglobulin E
MMR—measles, mumps, and rubella
OR—odds ratio
PARSIFAL—Prevention of Allergy–Risk Factors for Sensitization in Children Related to Farming and Anthroposophic Lifestyle

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THE PREVALENCE OF immunoglobulin E (IgE)-mediated allergic disease in children has increased during the past decades,^{1,2} although recent reports suggest that the occurrence has stabilized.^{3,4} Because allergic diseases mostly debut in childhood, it is of great interest to study exposures that occur early in life and could have an effect on the maturation of the immune system.

The occurrence of many types of childhood infections has decreased markedly during past decades because of

better hygiene and vaccinations, which has coincided with the increase of allergic disorders.⁵ This suggests that certain infections might have a role in the development of allergy. Infection with the measles virus may have an immune-suppressive effect⁶ and might affect the development of allergy. However, studies on the impact of measles infection on allergic disease have shown conflicting results.^{7–18} The timing of infection,¹⁴ differences in outcome definitions, as well as methodologic limitations might be of importance for the apparently discrepant findings. When measles vaccination was introduced in the 1970s, the incidence of measles infection decreased dramatically.¹⁹ Measles vaccine has been associated with the development of allergic disease, but the evidence seems inconsistent.^{5,8–10,13,16,20–23}

In a previous study on Steiner-school children, who have a lower prevalence of allergic disease, we found that measles infection was associated with a lower risk of atopic eczema in sensitized children.¹⁶ Furthermore, measles vaccination was associated with an increased risk of rhinoconjunctivitis. Steiner-school children often have an anthroposophic lifestyle that is characterized by restricted use of antibiotics, antipyretics, and vaccinations, and by high consumption of biodynamic foods.^{16,24} Biodynamic farming differs from conventional farming by less use of chemical-synthetic pesticides and fertilizers.

The aim of this study was to investigate the role of measles vaccination and measles infection for allergic disease and atopic sensitization in children of the Prevention of Allergy–Risk Factors for Sensitization in Children Related to Farming and Anthroposophic Lifestyle (PARSIFAL) study, which included farm children, Steiner-school children, and reference children.

MATERIALS AND METHODS

This work was based on the PARSIFAL study, a cross-sectional, multi-center study performed in 5 European countries (Austria, Germany, the Netherlands, Sweden, and Switzerland). The children were 5 to 13 years of age, and born between 1987 and 1996. The study has been described in detail elsewhere.²⁵ In brief, 4 groups of children were selected for the study: children living on a farm, children attending Steiner schools, as well as 2 reference groups (children from nonfarming households [farm reference children] and children from non-Steiner schools [Steiner reference children]). In total, 14 893 children (69% response rate) participated in the study. Information about environmental exposures, history of vaccinations and infections, lifestyle factors, as well as symptoms and diagnoses of allergic diseases were collected through a parental questionnaire. Most questions were based on the internationally standardized and validated International Study of Asthma and Allergies in Childhood phase II protocol,³ or derived from previous studies.^{24,26,27} Blood samples were provided by 4049 (83% response rate) children invited for blood sampling and required parental consent. Because of a large number of children included in the questionnaire surveys in Germany and Switzerland, a random sample of eligible children was selected in these countries. A total of 3979

samples yielded a sufficient volume for allergen-specific IgE measurements. The study was approved by local ethics committees in the participating countries.

Definition of Exposures and Health Outcomes

Measles vaccination was defined as a positive answer to the question “Has the child been vaccinated against measles?” and in the same way, measles infection was considered if the question “Has the child had measles infection?” was answered positively.

All health outcomes were reported by the parents, except atopic sensitization, which was assessed from blood sampling. Current rhinoconjunctivitis symptoms were defined as sneezing, runny nose, nasal block-up, and itchy eyes in the child during the last 12 months without having a cold at the same time. Children diagnosed with hay fever and who ever had symptoms of hay fever were considered to have a physician’s diagnosis of rhinoconjunctivitis. Current wheezing was defined as having wheezing at least once during the last 12 months. Children ever diagnosed with asthma, or obstructive bronchitis more than once, were considered to have a physician’s diagnosis of asthma. Current atopic eczema symptoms were present if the child ever had had an itchy rash intermittently for at least 6 months, and if the child had had an itchy rash during the last 12 months. Children diagnosed with atopic eczema and who ever had an itchy rash lasting at least 6 months were considered to have a physician’s diagnosis of atopic eczema. If the child had symptoms of at least 1 allergic disease (ie, current rhinoconjunctivitis symptoms, current wheezing, and/or current atopic eczema symptoms), he or she was considered to have “any allergic symptom,” and “any diagnosis of allergy by a physician” was defined correspondingly.

Atopic sensitization was indicated if the child had at least 1 allergen-specific serum IgE result of ≥ 0.35 kU/L against common inhalant allergens (Phadiatop; Pharmacia, Uppsala, Sweden: birch, timothy, mugwort, *Dermaphagoides pteronyssinus* and *farinae*, cat-, dog-, and horse epithelium, and *Cladosporium herbarum*) and/or food allergens (F_x5: egg white, milk, fish, wheat, peanut, and soy) (ImmunoCAP System; Phadia AB, Uppsala, Sweden). In addition, a cutoff value of ≥ 3.5 kU/L was used in some analyses. All IgE analyses were performed at the Department of Clinical Immunology, Karolinska University Hospital Solna, Stockholm, Sweden.

Statistical Methods

The relation between measles vaccination and/or measles infection and allergic disease or atopic sensitization was calculated by using odds ratios (ORs) and 95% confidence intervals (CIs) computed from logistic regression. Data were analyzed in models adjusted for age (5–6, 7–8, 9, 10–11, or 12–13 years), gender (boy or girl), center (Austria, Germany, the Netherlands, Sweden, or Switzerland), study group (farmer, Steiner, farmer reference, Steiner reference), smoking during pregnancy (yes, no), current environmental smoking (yes, no), mother with asthma and/or rhinoconjunctivi-

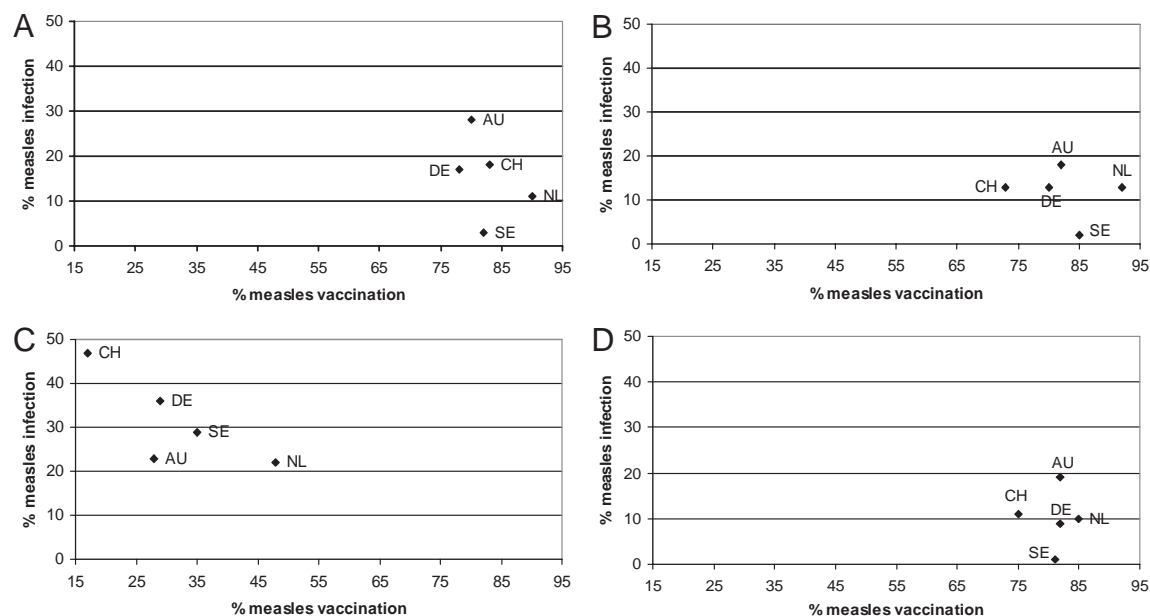


FIGURE 1

Prevalence of measles vaccination and measles infection among children in the PARSIFAL study divided according to group and country. A, Farm children; B, farm reference children; C, Steiner-school children; D, Steiner reference children. AU indicates Austria; CH, Switzerland; DE, Germany; NL, Netherlands; SE, Sweden.

tis (yes or no), father with asthma and/or rhinoconjunctivitis (yes or no), number of older siblings (0, 1, 2, or ≥ 3), parental education (elementary school, high school, university), and household pets during first year of life (yes, no). First, we analyzed the effect of measles vaccination and infection by using a combined variable with 4 categories (no vaccination or infection, vaccination but no infection, infection but no vaccination, or both vaccination and infection). Second, we performed separate analyses of measles vaccination and infection, 1 adjusted for the other, and vice versa. To reduce bias from disease-related modification of exposure, the data were analyzed in 2 steps. Initially, the effects of measles vaccination and measles infection were analyzed in the whole population, and then after exclusion of children with onset of wheezing and/or eczema during the first year of life ($n = 753$). Finally, analyses were also performed in groups defined by both symptoms/diagnoses and results of the IgE analyses to increase the specificity of the outcome definition in relation to allergy. Stata 8.0 software (Stata Corp, College Station, TX) was used for all statistical analyses. Statistical significance was defined as $P < .05$.

To be included in the analyses the questions on measles vaccination and measles infection had to be answered with "yes" or "no." A total of 2353 children were excluded because of incomplete answers ("do not know" or missing) to any of these questions. Thus, the analyses were based on 12 540 children, including 3378 children with blood samples.

RESULTS

The prevalence of measles vaccination and measles infection varied in the different groups and countries (Fig 1 A–D). In total, 9136 children (73%) were vaccinated

against measles, 2561 children (20%) had had measles infection, and 1815 children (14%) were neither vaccinated nor infected with measles. Overall, 11% ($n = 972$) of the children vaccinated against measles reported measles infection, with some variation between the countries (Austria, 13%; Germany, 6%; the Netherlands, 11%; Sweden, 1%; and Switzerland, 9%). Measles vaccination was least common among the Steiner-school children, and there were no significant differences between the other groups. The highest vaccination rate was found in the Netherlands, regardless of group belonging. Steiner-school children reported the highest prevalence of measles infection (33%). The lowest prevalence of measles infection was observed in Sweden, whereas in Austria and Switzerland the prevalence was relatively high. Measles vaccination is generally given in combination with mumps and rubella vaccines. In our data, 8206 (90%) of the children reporting measles vaccination also reported vaccination against mumps and rubella.

Table 1 shows the association between measles vaccination and/or infection and risk of allergic symptoms, physician's diagnoses, and atopic sensitization. We observed a statistically significant positive association between measles vaccination and rhinoconjunctivitis (symptoms and physician's diagnosed) among children who never had measles infection. In the subset of children with blood samples, we observed a trend toward inverse associations between measles vaccination, infection, or both, and atopic sensitization (at allergen-specific IgE level of ≥ 0.35 and ≥ 3.5 kU/L). Similar results were observed when inhalant allergens (Phadiatop) and food allergens (F_x5) were analyzed separately. When the analysis was based on measles, mumps, and rubella (MMR) vaccination, instead of measles vaccination, the

TABLE 1 Association Between Measles Vaccination, Measles Infection, or Both and Allergic Disease and Atopic Sensitization Among Children in the PARSIFAL Study

	Adjusted Models ^a							
	No Infection/No Vaccination		Vaccination/No Infection		Infection/No Vaccination		Vaccination and Infection	
	n/N ^b	Reference	n/N ^b	OR (95% CI)	n/N ^b	OR (95% CI)	n/N ^b	OR (95% CI)
All children ^c								
Current rhinoconjunctivitis symptoms	116/1670	1.0	569/7390	1.30 (1.02–1.66)	93/1438	0.80 (0.60–1.08)	44/835	1.00 (0.68–1.48)
Physician's diagnosis of rhinoconjunctivitis	59/1667	1.0	329/7356	1.70 (1.23–2.35)	53/1435	0.93 (0.63–1.39)	28/833	1.52 (0.92–2.51)
Current wheezing	134/1667	1.0	530/7395	0.96 (0.76–1.21)	130/1439	1.17 (0.90–1.52)	60/841	1.02 (0.72–1.44)
Physician's diagnosis of asthma	140/1662	1.0	671/7342	1.03 (0.83–1.29)	130/1427	1.04 (0.80–1.35)	60/819	0.84 (0.60–1.18)
Current atopic eczema symptoms	164/1673	1.0	780/7403	1.07 (0.87–1.32)	155/1430	1.12 (0.88–1.42)	73/841	0.95 (0.69–1.29)
Physician's diagnosis of atopic eczema	177/1664	1.0	748/7383	0.94 (0.77–1.15)	159/1425	1.08 (0.85–1.36)	74/842	0.88 (0.64–1.20)
Children with blood samples ^c								
Atopic sensitization (≥ 0.35 kU/L)	162/467	1.0	597/2042	0.83 (0.63–1.07)	133/409	0.87 (0.65–1.18)	61/219	0.67 (0.45–0.99)
Phadiatop (≥ 0.35 kU/L)	158/467	1.0	548/2042	0.79 (0.61–1.03)	127/409	0.81 (0.60–1.10)	55/219	0.62 (0.42–0.93)
Fx5 (≥ 0.35 kU/L)	66/467	1.0	241/2042	0.84 (0.59–1.20)	37/409	0.62 (0.40–0.96)	23/219	0.63 (0.36–1.09)
Atopic sensitization (≥ 3.5 kU/L)	99/467	1.0	334/2042	0.77 (0.56–1.06)	70/409	0.70 (0.49–1.01)	30/219	0.54 (0.33–0.88)

^a Adjustments were made for age, gender, center, study group, smoking during pregnancy, current environmental smoking, maternal asthma and/or rhinoconjunctivitis, paternal asthma and/or rhinoconjunctivitis, older siblings, parental education, and household pets during first year of life.

^b n indicates number of children with actual disease; N, number of children in the analysis.

^c All children = 12 540, of which 3378 provided a blood sample.

results remained the same. It should be noted that a majority of unvaccinated children who never had measles (ie, the reference category), as well as those with measles infection, were Steiner-school children (70% and 79%, respectively).

To reduce bias caused by disease-related modification of exposure, mainly regarding vaccination, we excluded children who reported symptoms of wheezing and/or eczema during the first year of life. The numbers in the symptom groups were small and, therefore, we performed analyses of measles vaccination and measles infection, respectively, combining outcomes as any allergic symptom and any diagnosis of allergy by a physician (Table 2). In analyses of all children, we observed inverse associations between measles vaccination and measles infection, respectively, and atopic sensitization, although statistically significant only for measles infection in relation to allergen-specific serum IgE level of ≥ 3.5 kU/L. There were no significant associations between measles vaccination or infection and any allergic symptom or any diagnosis of allergy by a physician. After excluding children with symptoms of wheezing and/or eczema during the first year of life, measles infection was inversely associated with any allergic symptom and any diagnosis of allergy by a physician, respectively, whereas the association with atopic sensitization was attenuated. There was no clear heterogeneity in results when the 4 study groups were analyzed separately; however, these analyses had low statistical power (data not shown).

To increase the specificity of symptoms/physician's diagnosis in relation to allergic disease, analyses were performed combining these with atopic sensitization (Table 3). Inverse associations were observed between measles vaccination and measles infection, respectively,

and having any allergic symptom or any diagnosis of allergy by a physician in combination with atopic sensitization, compared with nonsensitized children free from symptoms/physician's diagnoses, although statistically significant only for measles infection. Measles vaccination was positively associated with having any allergic symptom or a physician's diagnosis without being sensitized. After exclusion of children with symptoms of wheezing and/or eczema during the first year of life, no association remained statistically significant.

DISCUSSION

In our study, including children of farming and anthroposophic families in 5 European countries, inverse associations were indicated between measles infection or vaccination and atopic sensitization in the whole group of children. This association tended to be stronger for an IgE cutoff level of 3.5 kU/L compared with 0.35 kU/L. After exclusion of children with early debuting symptoms of wheezing and/or eczema, this association was attenuated. However, in these analyses, measles infection was inversely associated with any allergic symptom or physician's diagnosis of allergy, whereas there were no associations with measles vaccination. The change in result after exclusion of children with early symptoms may be a result of disease-related modification of exposure (eg, that parents of children with early symptoms of allergy avoided or postponed measles vaccination, and perhaps also measles infection, which might be the case among certain anthroposophic parents).

Disease-related modification of exposure is a potential problem in epidemiologic studies of measles vaccination and measles infection in relation to allergic diseases in children. However, most previous studies do not take

TABLE 2 Any Allergic Symptom, Any Diagnosis of Allergy by a Physician, or Atopic Sensitization in Relation to Measles Vaccination and Measles Infection Among Children in the PARSIFAL Study

	Adjusted Models ^a							
	Measles Vaccination				Measles Infection			
	Reference		Reference		Reference		Reference	
	n/N ^b	Reference	n/N ^b	OR (95% CI)	n/N ^b	Reference	n/N ^b	OR (95% CI)
All children ^c								
Any allergic symptom	647/3197	1.0	1685/8465	1.07 (0.93–1.22)	1858/9234	1.0	448/2325	0.97 (0.85–1.10)
Any diagnosis of allergy by a physician	605/3197	1.0	1588/8465	1.01 (0.88–1.17)	1758/9234	1.0	416/2325	0.94 (0.82–1.40)
Children with blood samples ^c								
Atopic sensitization (≥ 0.35 kU/L)	303/899	1.0	675/2307	0.83 (0.65–1.05)	763/2536	1.0	195/633	0.85 (0.68–1.06)
Atopic sensitization (≥ 3.5 kU/L)	175/899	1.0	373/2307	0.78 (0.58–1.04)	434/2536	1.0	100/633	0.70 (0.53–0.92)
Children with early symptoms excluded ^c								
Any allergic symptom	74/2094	1.0	236/5771	1.31 (0.92–1.88)	263/6297	1.0	47/1568	0.69 (0.48–0.99)
Any diagnosis of allergy by a physician	74/2094	1.0	211/5771	0.92 (0.64–1.32)	244/6297	1.0	41/1568	0.65 (0.45–0.95)
Children with blood samples ^c								
Atopic sensitization (≥ 0.35 kU/L)	153/586	1.0	355/1506	0.88 (0.63–1.22)	392/1662	1.0	116/430	1.05 (0.79–1.38)
Atopic sensitization (≥ 3.5 kU/L)	61/586	1.0	155/1506	1.04 (0.65–1.66)	171/1662	1.0	45/430	0.87 (0.58–1.31)

^a Adjustments were made for age, gender, center, study group, smoking during pregnancy, current environmental smoking, maternal asthma and/or rhinoconjunctivitis, paternal asthma and/or rhinoconjunctivitis, older siblings, parental education, household pets during first year of life, and measles infection and measles vaccination, respectively, in the model where it is not the main exposure.

^b n indicates number of cases; N, total number of children in the analysis.

^c In total, 12 540 children were included in the analyses, of which 3378 provided a blood sample. The number of children with early symptoms of wheezing and/or eczema was 753 (211 among children with blood samples).

this into account. We found 6 articles that assessed exposures before outcomes. One study observed an increased risk of asthma after MMR vaccination,⁵ whereas another reported an increased risk of atopic dermatitis after either measles vaccination or infection.⁹ Some studies found no relation between measles infection and allergic disease,^{13,14} or between measles vaccination and allergic disease.^{13,20,21} Thus, our result of an inverse association between measles infection and allergic disease seemed to differ from the results of these studies. It is possible that both methodologic issues, such as the way of controlling for disease-related modification of exposure, outcome definitions, and length of follow-up, as well as biological aspects related to timing of exposure and type of vaccine, etc, contribute to explaining the apparently conflicting results. Among studies that did not assess exposure before outcome, measles vaccination was positively,^{8,16} inversely,^{10,23} or not associated^{21,22} with allergic disease or atopic sensitization. The results were more constant for studies on the association between measles infection and allergic disease or atopic sensitization, where inverse associations^{7,8,10,12,16,17} dominated, compared with positive^{11,18} or no associations.¹⁵ The results seemed inconsistent also considering cohort studies^{5,7,21,23,28} and cross-sectional studies^{8,10,11,16–18,22} separately.

A major difficulty in studies on measles vaccination and measles infection in relation to allergic disease in children is to assess the time sequence of events, that is, if the exposure precedes the disease or not. This is especially difficult in cross-sectional studies. There are different ways to deal with this problem, and it can be done at

different stages of the study, for example, to collect data on vaccination/infection prospectively (design stage), or to group subjects according to age of exposure/outcome if that information is available (analysis stage), or to exclude subjects for whom the information on timing of the exposure/outcome is incomplete (analysis stage). However, even in prospective studies there may be a risk that certain characteristics related to the outcome, eg, allergy among family members, may confound the association between exposure and outcome.

In the PARSIFAL study, 11% of all children vaccinated against measles also reported measles infection, and the prevalence of children who were both vaccinated and infected with measles differed substantially between the countries. This may be explained by differences in vaccination coverage,²⁹ year of introduction of the vaccine,¹⁹ and recurrent measles epidemics.²⁹ Some children in our study presumably received only 1 dose, which makes it easier for vaccinated children to get infected.²⁹ Table 4 presents World Health Organization statistics of MMR vaccination during the study period in 4 countries³⁰ and data from the Robert-Koch Institute for Germany. The data correspond well with the prevalence of measles vaccination in the PARSIFAL study and contribute to explaining the difference in prevalence of measles infection in the different countries. For example, MMR vaccination was introduced early in Sweden and vaccination coverage has been high, which is in line with the low prevalence of measles infection observed in the Swedish part of the PARSIFAL study. It should be noted that an article on MMR vaccination and autism was published 2 years before the data collection in our

TABLE 3 Any Allergic Symptom or any Diagnosis of Allergy by a Physician Combined With Atopic Sensitization (0.35 kU/L) in Relation to Measles Vaccination and Infection, Among Children With Blood Samples in the PARSIFAL Study

	Adjusted Models ^a							
	Measles Vaccination				Measles Infection			
	Reference				Reference			
	n/N ^b		n/N ^b	OR (95% CI)	n/N ^b		n/N ^b	OR (95% CI)
All children ^c								
Any allergic symptom								
No symptoms and no sensitization	510/876	1.0	1347/2261	Reference	1485/2509	1.0	372/628	Reference
Symptoms and no sensitization	65/876	1.0	228/2261	1.42 (0.95–2.13)	217/2509	1.0	55/628	1.05 (0.74–1.51)
No symptoms and sensitization	166/876	1.0	384/2261	0.94 (0.70–1.27)	483/2509	1.0	125/628	1.01 (0.78–1.31)
Symptoms and sensitization	123/876	1.0	264/2261	0.76 (0.54–1.07)	264/2509	1.0	66/628	0.64 (0.46–0.90)
Any diagnosis of allergy by a physician								
No diagnosis and no sensitization	515/876	1.0	1350/2261	Reference	1496/2509	1.0	369/628	Reference
Diagnosis and no sensitization	55/876	1.0	214/2261	1.90 (1.24–2.91)	217/2509	1.0	52/628	1.12 (0.77–1.62)
No diagnosis and sensitization	188/876	1.0	438/2261	1.06 (0.80–1.42)	483/2509	1.0	143/628	1.04 (0.81–1.34)
Diagnosis and sensitization	96/876	1.0	212/2261	0.69 (0.48–1.01)	264/2509	1.0	44/628	0.51 (0.35–0.75)
Children with early symptoms excluded ^c								
Any allergic symptom								
No symptoms and no sensitization	428/586	Reference	1129/1506	Reference	1245/1662	Reference	312/430	Reference
Symptoms and no sensitization	3/586	1.0	15/1506	2.43 (0.53–11.0)	18/1662	1.0	0/430	—
No symptoms and sensitization	135/586	1.0	308/1506	0.86 (0.61–1.22)	338/1662	1.0	105/430	1.06 (0.79–1.41)
Symptoms and sensitization	16/586	1.0	45/1506	1.55 (0.64–3.76)	27/1662	1.0	10/430	0.79 (0.34–1.81)
Any diagnosis of allergy by a physician								
No diagnosis and no sensitization	423/586	Reference	1099/1506	Reference	1219/1662	Reference	303/430	Reference
Diagnosis and no sensitization	5/586	1.0	27/1506	2.57 (0.73–9.11)	28/1662	1.0	4/430	0.56 (0.17–1.77)
No diagnosis and sensitization	138/586	1.0	329/1506	1.01 (0.72–1.43)	358/1662	1.0	109/430	1.06 (0.80–1.42)
Diagnosis and sensitization	9/586	1.0	21/1506	0.51 (0.17–1.55)	27/1662	1.0	3/430	0.46 (0.12–1.79)

^a Adjusted for age, gender, center, study group, mother with asthma and/or rhinoconjunctivitis, father with asthma and/or rhinoconjunctivitis, older siblings, pets during first year of life, current environmental smoking, mother's smoking during first year of life, parental education, and measles infection or measles vaccination, respectively, in the model where it is not the main exposure.

^b n indicates number of cases; N, total number of children in the analysis.

^c In total, 3378 children provided a blood sample. The number of children with early symptoms of wheezing and/or eczema was 211 among those who provided a blood sample.

study,³¹ which may have affected the vaccination rates in some countries.

The strength of the PARSIFAL study is its large size with multinational design, although the cross-sectional design is not optimal for elucidation of the temporal relation between measles vaccination/infection and allergic disease. Another strength of our study is the comparatively high prevalence of children who contracted measles infection (20%), especially because measles usually is now a rare disease in industrialized countries.⁶ A limitation of the study is the low prevalence of allergic disease and atopic sensitization in the reference category (unvaccinated children without measles infection), which consisted mostly of

Steiner-school children. The positive association between measles vaccination and current rhinoconjunctivitis could be the result of this difference in disease prevalence.

Misclassification of exposure might affect the results. In our material, the child's vaccination status was based on parental recall, which has been associated with both underestimation and overestimation in validity studies.^{32,33} The typical symptoms of measles infection, high fever and characteristic skin rash, are often distinct and appear in epidemics, which helps to make parental reports of measles infection reliable. To the extent that the misclassification was nondifferential, it would not change the direction of our observed associations. Un-

TABLE 4 World Health Organization Statistics³⁰ of Monovalent and Combined Measles Vaccination Between 1988 and 1998

Country	Introduction of Monovalent Measles Vaccine in the Vaccination Program, 1 Dose, Year	Introduction of MMR Vaccination in the Vaccination Program, Year		Mean Vaccination Coverage		Recommended Age for First and Second Dose	
		First Dose	Second Dose	First Dose, %	Second Dose	First Dose, mo	Second Dose, y
Austria	1974	1994	1998	60–90	NI	14	6–7 ^a
Germany ^b	1972	1988	1993	47–89	NI	15	6
Netherlands	1976	1987	1987	93–96	NI	14	9
Sweden	1971	1982	1982	94–97	NI	18	12 ^a
Switzerland	1976	1985	1996	70–90	NI	15–24	4–7

Relevant comparison period for children in the PARSIFAL study who were born between 1987 and 1996. NI indicates no information.

^a Since 2006, the second dose is recommended 1 month after the first dose in Austria, or at age 6 in Sweden.

^b German data were obtained from the Robert-Koch Institute.

fortunately, we did not have information on the child's age at measles infection and, therefore, could not investigate if the allergic symptoms/atopic sensitization or the measles infection came first. Moreover, among Steiner reference children, the prevalence of allergic disease tended to be higher among children who provided a blood sample compared with those who did not.²⁵ This might bias our results on atopic sensitization or allergic symptoms/diagnoses in combination with atopic sensitization. To assess the magnitude of this potential bias, we adjusted the analyses for symptoms/disease prevalence, which resulted in small effects on the observed ORs, speaking against a major role of selection bias. Furthermore, we cannot exclude that our results are influenced by the other vaccines included in the MMR vaccination, or the different vaccination routines of Steiner-school children, with fewer vaccinations and that are often given later than recommended by the health authorities.²⁴ Moreover, we can not exclude the possibility that other factors in the anthroposophic lifestyle may influence the observed associations.¹⁶

CONCLUSIONS

We observed an inverse association between measles infection and any allergic symptoms and any diagnosis of allergy by a physician in children, after excluding children with early symptoms of wheezing and eczema. Most studies on measles vaccination and measles infection in relation to allergic disease have not considered the time sequence of events, and therefore causal associations should be further investigated in prospective cohort studies.

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Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection

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Exhibit J

Frequency of allergic diseases following measles

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ABSTRACT

Objective: Viral and bacterial infections in childhood decrease the likelihood of allergic diseases in later life. The frequency of allergic diseases in patients with a history of measles has been reported to be low but some studies still suggest that measles can increase the frequency of allergic diseases.

Methods: Fifty-two children hospitalized in our clinic with measles were compared with 51 children without measles. Allergic diseases were investigated in both groups by using the International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire. In all children, allergy skin tests were performed with the four most common allergens.

Results: Sensitivity to *Dermatophagoides pteronyssinus* was less frequent in children with measles than in those without ($p < 0.05$). A history of nebulized salbutamol use in the emergency room in the previous 12 months was also less frequent in the measles group ($p < 0.05$). Inhaled corticosteroid use was more common in the group without measles ($p < 0.05$).

Conclusion:

These children were less sensitive to *D. pteronyssinus*.

Key words: Allergic rhinitis. Asthma. Atopic dermatitis. Measles. Skin prick test. Wheezing.

INTRODUCTION

The prevalence of allergic diseases is steadily increasing in our country similar to the increase throughout the world¹⁻⁴. Allergic diseases are known to be more frequent in Western countries⁵⁻⁷. Similarly, the prevalence of atopy diagnosed by the skin prick test and specific IgE is also on the increase^{8,9}. These findings may be attributed to the hygiene hypothesis, which suggests an increase in the frequency of atopic diseases due to the decreasing number of children in families and a fall in the number of infections^{10,11}. According to this hypothesis, the cytokine profile with an innate predominance of allergenic Th2 profile, shifts to the non-allergenic Th1 profile with the influence of childhood infections^{12,13}. Although a number of studies demonstrate that measles and other viral infections prevent allergic conditions, other reports suggesting an increase in allergic diseases due to these infections are also present¹⁵⁻²⁰. Turkey is a country with a high prevalence of childhood diseases. The number of measles cases was 30,509 in 2001 and the morbidity rate was 44.97 per one hundred thousand²¹.

We aimed to investigate the correlation of allergic diseases with a history of measles.

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METHODS

Fifty-two children with a diagnosis of measles who were hospitalized in the Pediatric Infectious Diseases Clinic in the Okmeydanı Teaching hospital during 1996 and 2002 were incorporated into the study. The control group consisted of fifty-one children who had been admitted to the outpatient clinic for other reasons and did not have a history of measles or a chronic disease. The diagnosis of measles was based on the presence of a maculopapular rash, high fever, rhinitis, conjunctivitis, cough, and Koplik spots on the buccal mucosa. Control cases without a history of measles were selected randomly among cases admitted to the pediatric outpatient clinic for other reasons. The number of measles vaccinations was recorded according to the children's vaccination cards.

The "International Study of Asthma and Allergies in Childhood" (ISAAC) questionnaire was applied to both groups. Sociodemographic questions were also asked. The parents of children enrolled in the study gave verbal consent. Prick skin tests with four allergens—*Dermatophagoides pteronyssinus*, *Mixture5 Grasses*, *Alternaria* and cockroach antigens (Staller-genes, France) were performed. Sterile saline and histamine (10 mg/dl) were used as negative and positive controls respectively in the prick test simultaneously with the above-mentioned allergens. Tests results were evaluated 15 minutes after the procedure. The endurance diameter for each allergen was subtracted from that of the negative control and a resulting endurance of ≥ 3 mm was interpreted as positive. Moreover, when the endurance diameter of the allergen was subtracted from that of the negative control and the resulting number was divided by the endurance diameter of histamine, a value of at least 0.5 was also considered positive.

Statistical analyses were run with SPSS for windows. Fisher's exact test and independent t test were used for inter-group comparisons. A p value of < 0.05 was considered statistically significant.

RESULTS

The comparisons of age, height and weight in both groups did not yield a significant difference (table I). While the mean number of measles vaccinations was 0.94 in the measles group, it was 1.90 in the group without measles. The number of children living in the house was significantly higher in the measles group, compared to that of the control group.

The number of children using inhalation corticosteroids was significantly higher in the group without

Table I

Comparison of characteristics of the measles group and the control group

	Cases with measles (n = 52)	Cases without measles (n = 51)	p*
Age (years)	6,65 \pm 1,85	6,57 \pm 2,08	> 0,05
Weight (kg)	21,18 \pm 5,68	20,11 \pm 5,50	> 0,05
Height (cm)	117,04 \pm 11,77	115,50 \pm 13,58	> 0,05
Number of measles vaccinations	0,94 \pm 0,96	1,90 \pm 0,36	< 0,0001
Number of children living in the house	3,02 \pm 1,48	2,35 \pm 0,91	< 0,01

*Student's-t test.

measles than in the measles group ($p < 0.05$) (table II). There were significantly more children with a history of allergic dermatitis in the control group, compared to the group with measles ($p < 0.05$).

The primary attack of wheezing was significantly earlier in the measles group (table III).

History of experiencing a wheezing attack and use of nebulized salbutamol in the previous 12 months was significantly less frequent in the measles group (table III).

While the positivity of *D. pteronyssinus* allergy skin test was significantly higher in the group without measles, there was no significant difference between the two groups with regard to the results of other allergy skin tests (table IV).

DISCUSSION

Up to date, conflicting results on the correlation between allergic diseases and childhood infections have been obtained. While some reports suggest that childhood infections prevent the development of allergic diseases, others claim that they increase the frequency of these conditions¹⁴⁻²⁰. However, general opinion is that viral infections in childhood prevent the occurrence of asthma. A multi-center cohort study in Germany indicates that recurrent viral upper respiratory tract infections early in life decrease the likelihood of asthma, whereas a positive correlation is present between recurrent lower respiratory tract infections and wheezing attacks²². Authors attribute this to the predilection of the immature immune system towards Th1 phenotype with the stimulation of recurrent viral infections in early childhood, which consequently decreases the likelihood of asthma during the pre-school period²². Similarly, in vitro stud-

Table II
Comparison of various characteristics of the measles group and the control group

	Cases with measles (n = 52) (%)	Cases without measles (n = 51) (%)	p*
Allergic disease in the family	17 (32,6)	15 (29,4)	> 0,05
Allergic disease in the mother	9 (17,3)	5 (9,8)	> 0,05
Allergic disease in the father	3 (5,7)	3 (5,9)	> 0,05
Allergic disease in siblings	3 (5,7)	7 (13,7)	> 0,05
Case admitted to receive nebulized salbutamol in the emergency room	18 (34,6)	20 (39,2)	> 0,05
History of wheezing	29 (55,7)	29 (56,8)	> 0,05
Wheezing within the previous 12 months	11 (21,1)	14 (27,4)	> 0,05
History of inhaled steroid use	3 (5,8)	8 (15,6)	> 0,05
Current use of inhaled steroids	1 (2)	6 (13,3)	< 0,05
Allergic rhinitis findings within the previous 12 months	4 (7,7)	7 (13,7)	> 0,05
Allergic conjunctivitis findings within the previous 12 months	1 (2)	2 (3,9)	> 0,05
History of atopic dermatitis	-	4 (7,8)	< 0,05
Atopic dermatitis within the previous 12 months	-	3 (5,9)	> 0,05
Physician's diagnosis of asthma	1 (2)	3 (5,9)	> 0,05
Physician's diagnosis of allergic rhinitis	-	2 (3,9)	> 0,05
Physician's diagnosis of allergic dermatitis	-	1 (1,9)	> 0,05

*Fisher's exact test.

Table III

**Comparison of the two groups with regard to a history
of nebulized salbutamol use within the previous
12 months**

Use of nebulized salbutamol	Cases with measles (n = 52) (%)	Cases without measles (n = 51) (%)	p*
Never	8 (15,3)	3 (5,8)	< 0,05
1-3 times	3 (5,7)	7 (13,7)	
4 times or more	-	3 (5,8)	

*Fisher's exact test

Table IV

Comparison of allergy skin tests between the two groups

Skin test positivity	Measles (+) (n = 52)	Measles (-) (n = 51)	p*
Total	4 (7,7 %)	8 (15,7 %)	> 0,05
<i>D. pteronyssinus</i>	2 (3,8 %)	8 (15,7 %)	< 0,05
Mixture 5 grasses	0 (0 %)	3 (5,9 %)	> 0,05
<i>Alternaria</i>	1 (1,9 %)	2 (3,9 %)	> 0,05
Cockroach	1 (1,9 %)	2 (3,9 %)	> 0,05

*Fisher's exact test.

ies suggest that bacterial and viral infections prevent atopy by increasing the production of γ -interferon by Th1 type T lymphocytes^{23,24}. This cytokine prevents the development of atopy, ensuring the transformation of Th0 to Th1 instead of Th2.

In a study in Guinea Bissau, 395 children aged six years or younger were followed up for 14-16 years. Allergic diseases were 50 % less frequent in children who had contracted measles than in those who had not¹⁴. The hypothesis that measles prevented allergic diseases was investigated in Finland by evaluating

medical records between 1982 and 1986²⁰. Of the 547 910 children aged between 14 months and 19 years, 20 960 had experienced measles and the remaining had not. The results of the study showed that allergic diseases were more frequent in cases with measles. The results of this study were not consistent with the hypothesis that measles could prevent allergic diseases. The higher frequency of allergic diseases in cases with a history of measles was attributed to genetic predisposition. Another report from Denmark revealed that children vaccinated for

measles, rubella and varicella were not protected from atopy even when they were exposed to these infections during childhood²⁵.

The present study investigated the correlation between measles and atopy by comparing two groups of children with and without measles. Sensitivity to *D. pteronyssinus*—the most common cause of allergy—was more frequent in the control group without measles. While the *D. pteronyssinus* allergy skin test was positive in only two patients (3.8 %) in the measles group, 8 patients (15.7 %) were positive in the control group. The mean number of measles vaccinations was less than one in the measles group and almost two in the control group. A significant difference was present between the two groups in terms of age at which the wheezing episode first occurred. The age at which measles was contracted was three in the measles group. The age at which the first wheezing episode occurred in this group was less than two in 48 % of the cases; this percentage dropped to 4 % between the ages 2 and 4. No primary wheezing episode in this group was detected after the age of four. This decrease corresponds to the post-measles period. On the other hand, the decrease due to aging was slower in the control group. The history of experiencing a wheezing episode and receiving salbutamol in the emergency room during the previous 12 months was higher in the control group. Three children in the measles group and 10 children in the control group had received salbutamol in the emergency room; this difference was statistically significant ($p < 0.05$).

In conclusion, children with a history of measles in our study group had less frequent symptoms of allergic diseases. In children without a history of measles, sensitivity develops, particularly to the house dust mite.

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Exhibit K

MEASLES INFECTION AND PARKINSON'S DISEASE

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Sasco, A. J. (Harvard School of Public Health, Boston, MA 02115), and R. S. Paffenbarger, Jr. Measles infection and Parkinson's disease. *Am J Epidemiol* 1985;122:1017-31.

A case-control analysis of Parkinson's disease and infections in childhood was conducted in a cohort of 50,002 men who attended Harvard College (Cambridge, MA) or the University of Pennsylvania (Philadelphia, PA) between 1916 and 1950 and who were followed in adulthood for morbidity and mortality data. Cases of Parkinson's disease were identified from responses to mailed questionnaires and death certificates through 1978. Four controls from the same population were selected for each case. A reduced risk of Parkinson's disease was associated with most childhood viral infections. The negative association was statistically significant for a history of measles prior to college entrance (exposure odds ratio = 0.53; 95% confidence limits: 0.31, 0.93). The reduced risk of Parkinson's disease among subjects with a positive history of measles in childhood may reflect an adverse effect of measles in adulthood or of subclinical or atypical measles. Furthermore, a negative history of measles, especially if associated with a lack of other common diseases, could be a marker for negative influenza history before 1918 and thus a higher risk of infection during the 1918 influenza epidemic, because of the lack of partial influenza immunity. These data may also suggest a truly protective effect of measles, compatible with some complex interaction between measles virus and the virus of the 1918 influenza epidemic.

influenza; measles; Parkinson's disease; virus diseases

Parkinson's disease, a neurologic disorder involving the extrapyramidal system, was described for the first time in 1817 by James Parkinson (1). It is biochemically characterized by a decrease in the dopa-

mine content of the striatum. The classic clinical form consists of akinesia, rigidity, and tremor (2). A distinction is made between primary and secondary parkinsonisms. Primary parkinsonism refers to cases

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Abbreviations: CL, confidence limits; EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

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disease in former college students.

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of unknown etiology, representing the majority of Parkinson cases at this time. Secondary parkinsonism is categorized in several subgroups. The postencephalitic cases have been related to the epidemic of von Economo encephalitis (encephalitis lethargica) from 1918 to 1926 (3-5). A viral etiology common to both encephalitis lethargica and the 1918 pandemic influenza has been proposed (6). Iatrogenic parkinsonism occurs after use of certain drugs, such as phenothiazines and reserpine (7, 8). Occupational exposure to carbon monoxide, carbon disulfide, certain industrial solvents, mercury, and lead has been implicated (9, 10). Secondary parkinsonism has also been associated with arteriosclerosis. The roles of von Economo's disease and of arteriosclerosis in the etiology of Parkinson's disease are controversial (5, 6, 11-13).

Between 1967 and 1969, Kessler conducted two studies (14, 15) among Parkinson's disease patients to investigate the possibility of relation with various exposures, as well as the association with many diseases, including childhood viral infections. Using a case-control approach, in one study, hospitalized cases were compared with hospitalized controls (14) and, in another, nonhospitalized cases were compared with nonhospitalized population controls (15). The investigator reported that cases were less likely than controls to give a history of chickenpox, measles, German measles, and mumps. The results were based on self-reports at the time of Parkinson's disease. The associations did not attain statistical significance and were less marked with population controls (relative risk for chickenpox, 0.79; measles, 0.84; German measles, 0.93; and mumps, 0.77) than with hospital controls (relative risk for chickenpox, 0.61; measles, 0.75; German measles, 0.61; and mumps, 0.68).

This paper is concerned with the relationship between childhood diseases, mainly viral, and subsequent risk of Parkinson's disease. Other exposures will be reported in subsequent papers.

MATERIALS AND METHODS

Source population

This study is based on a cohort of 36,505 men who entered Harvard College (Cambridge, MA) between 1916 and 1950, and 13,497 men who attended the University of Pennsylvania (Philadelphia, PA) between 1931 and 1940. College records of these 50,002 subjects were searched for medical, social, psychologic, academic, and extra-academic data. For this study, the main source of information on exposure is the medical evaluation conducted at the time of college entrance. Each subject was expected to undergo an extensive medical interview and a thorough medical examination. At Harvard, each subject was to be seen by one of several physicians who completed the totality of the examination and information gathering. At the University of Pennsylvania, students were to be seen by a series of physicians, each of them concentrating on one body system. At both institutions, the findings were recorded on a standard form, requiring the recording of the presence or absence of a list of specified conditions.

As part of the medical history, information was requested of each subject on the most common childhood viral diseases: chickenpox, measles, and mumps, with indication of the age at infection. Information on German measles was included only at Harvard from 1940 to 1950. Information on influenza was recorded at both universities, but only until 1940. Bacterial diseases were also recorded, including diphtheria, pertussis, and scarlet fever, at both universities and rheumatic fever only at Harvard. Pneumonia, without specification of its viral or bacterial etiology, was reported, as well as tonsillectomy. Additional diseases or procedures could be added to the standard list if indicated by the subject at the time of the examination. Information was also recorded on family history of diseases, such as cardiovascular conditions or diabetes. Parental age and, if appropriate, parental cause of death, were stated. Lifestyle infor-

mation included data on smoking behavior, coffee and tea intake, and sports participation.

A complete physical examination was performed on each subject. The major physiologic parameters (height, weight, systolic and diastolic blood pressure, and pulse rate) were recorded, as well as signs and symptoms by systems. Laboratory investigations were also performed, but they varied with institution and time of college entrance.

Some subjects did not have the medical interview and examination, and some records have been lost or transferred to other schools within the university. No college medical information is available for them.

Follow-up information on former college students was provided through the alumni offices of both universities. Mailing lists are regularly updated, and it has been estimated that less than 1 per cent of alumni deaths are unknown to the alumni offices (16). Upon notification of death, death certificates were obtained, and information on cause of death or accompanying condition or both was recorded.

In addition to mortality data, morbidity data and lifestyle information in the postcollege days have been collected through mailed questionnaires, with an approximate response rate of 70 per cent. Morbidity data were obtained through the question, "Did a doctor ever tell you that you had any of the following?," applying to a list of conditions including Parkinson's disease. The year of onset was to be indicated. Such a questionnaire, by itself, or in combination with a request for information on lifestyle, was sent to the Harvard alumni in 1972 and in 1977-1978, and to the University of Pennsylvania alumni in 1976. Each subject was also invited to give his physician's name and address, along with permission to contact the physician for validation of self-reported conditions or for additional information.

Study design

Given the exploratory nature of this study, aiming at the testing of several hy-

potheses regarding the etiology of Parkinson's disease, a case-control approach was preferred over a more expensive cohort analysis. The availability of more than one matched control per case permits retention of most of the statistical efficiency, while considerable savings was made possible by restriction of the validation procedure to cases and controls, as opposed to the whole cohort.

Cases

Cases of Parkinson's disease for this study were identified from two sources, death certificates and responses to the questionnaires through 1978. Only subjects for whom we had the information described above taken at the time of college entrance were included as cases. Virtually all study subjects from both Harvard and the University of Pennsylvania were white.

We identified 136 potential cases from Harvard and 24 potential cases from the University of Pennsylvania. Of these, 114 Harvard and 23 University of Pennsylvania subjects had a medical evaluation at college, and information recorded on childhood diseases was available for them. The others were excluded because information taken at the time of college entrance was not available. The source of identification of the 137 cases retained in the analysis is given in table 1.

Controls

Four controls were selected for each case. They were subjects who were self-reported as not having Parkinson's disease, as of the 1976 University of Pennsylvania questionnaire or the 1977-1978 Harvard questionnaire. From the pool of subjects who attended the same institution as the case and with a college examination year and age at examination within two years of those of the case, four controls were randomly selected. Thus, controls were matched to the case on institution attended, year of college examination, and age at examination. This leads to a matching on year of birth, within two years for most of the cases and within

TABLE 1

Distribution of Parkinson's disease cases by source of identification: former Harvard College and University of Pennsylvania students, 1916-1978

	No.	%
Harvard College cases		
1972 questionnaire only	13	11.4
1977-1978 questionnaire only	51	44.7
Death certificate only	18	15.8
1972 and 1977-1978 questionnaires only	23	20.2
1972 questionnaire and death certificate only	8	7.0
1972 and 1977-1978 questionnaires and death certificate	1	0.9
Total	114	100.0
University of Pennsylvania cases		
1976 questionnaire only	20	87.0
Death certificate only	2	8.7
1976 questionnaire and death certificate	1	4.3
Total	23	100.0

TABLE 2

Distribution of Parkinson's disease cases by validation status: former Harvard College and University of Pennsylvania students, 1916-1978

	No.	%
Harvard College cases		
1975 validation only	8	7.0
1982 validation only	37	32.5
Death certificate only	23	20.2
1975 validation and death certificate only	3	2.6
1975 and 1982 validations only	12	10.5
No validation	31	27.2
Total	114	100.0
University of Pennsylvania cases		
1982 validation only	9	39.1
Death certificate only	4	17.4
No validation	10	43.5
Total	23	100.0

five years for all, except for one subject who entered college at age 32 years and for whom four controls matched within five years could not be found. Only controls with information taken at the time of college entrance were included in the study.

Validation of the Parkinson's disease status

We considered as validated any case which was confirmed by a physician. Validation by a neurologist was not required. All cases identified through death certificates with mention of Parkinson's disease were considered as validated. Validation of the cases identified through a self-report of Parkinson's disease on a questionnaire was sought by requesting confirmation of the diagnosis and of the date of onset from the subject's physician.

For the Harvard cases identified through the 1972 questionnaire, such a validation was done in 1975 for Parkinson's disease, as well as for other self-reported conditions. For all cases identified through any ques-

tionnaire and still alive, validation was done again in 1982. Combining the three possible validation procedures, the diagnoses of 83 of 114 Harvard cases (72.8 per cent) were confirmed, none was refuted, and no validation could be obtained for 31 cases. For the University of Pennsylvania cases, 13 cases were confirmed (56.5 per cent), none was refuted, and no validation could be obtained for 10 cases. The discrepancy in validation rates between Harvard College and the University of Pennsylvania may result in part from a prior attempt at validation in 1975 done only for the Harvard subjects (table 2).

Validation of the disease-free status of each control was also sought by confirmation from the subject's physician. The validation rates were 52.4 per cent for Harvard and 61.9 per cent for the University of Pennsylvania. None of the controls for whom the validation was completed had Parkinson's disease at the time of identification of the case to which he was matched, although two of the controls later developed Parkinson's disease.

Methods

Maximum likelihood estimates of the exposure odds ratio (EOR_{ML}) were computed

for each of the factors of interest. The analyses were done both matched and unmatched. Ninety-five per cent confidence limits were derived using Miettinen's test-based limits (17). Most analyses were performed with the calculator programs developed by Rothman and Boice (18). Multivariate analysis was based on the logistic regression model described by Cox (19) using a program for matched data developed by Dr. Bernard Rosner of the Harvard Medical School.

Preliminary analyses were done separately for the Harvard and the University of Pennsylvania groups. The results were very similar, and the stratification by institution was not retained for most of the unmatched analyses. The analyses were also conducted separately for cases identified through death certificates and cases identified from morbidity questionnaires. The analyses were finally done separately for cases still alive at the time of the 1976 University of Pennsylvania questionnaire or the 1977-1978 Harvard questionnaire, and cases who had already died or whose life status in 1976 or 1977-1978 was unknown. The exposure odds ratios for dead and alive cases, at the time of ascertainment or at the last questionnaire, were similar, and the stratifications by life status were not retained in most of the analyses.

RESULTS

Childhood diseases

Matched and unmatched exposure odds ratios and confidence limits for childhood diseases are presented in table 3. Since the results were very similar with the two procedures, the rest of the analysis, with the exception of the logistic regression, is presented unmatched.

For diphtheria, pertussis, and scarlet fever, the exposure odds ratios are very close to one. Rheumatic fever, on which information was available only at Harvard, appears as a possible risk factor for Parkinson's disease, although the result is not significant, and is based on only four ex-

posed cases. Bacterial diseases, with the possible exception of rheumatic fever, do not appear to have any impact on the subsequent risk of Parkinson's disease. The same applies to pneumonia, which may have a viral or bacterial etiology. For tonsillectomy, a surgical procedure usually performed on children who have repeated infections of viral or bacterial origin, the exposure odds ratio is slightly less than one.

A negative association exists between Parkinson's disease and most childhood viral infections. The exposure odds ratios are less than one for chickenpox ($OR_{ML} = 0.76$), measles ($OR_{ML} = 0.53$), and mumps ($OR_{ML} = 0.88$). For influenza, the exposure odds ratio is 1.1. German measles has an exposure odds ratio of 1.8, but this result is based on only four exposed cases, the information on the disease being available only for the subjects entering Harvard College between 1940 and 1950.

Measles

The only one of the above results with confidence limits (CL) that do not include the null value of 1.0 is the exposure odds ratio for measles. In these data, measles in childhood is associated with a reduced risk of Parkinson's disease. The values of the unmatched exposure odds ratios for measles are very similar, approximately 0.5, for the two institutions (Harvard College, 0.57; CL: 0.31, 1.1; University of Pennsylvania, 0.40; CL: 0.11, 1.4), for cases dead or alive at the time of identification (dead cases, 0.46; CL: 0.11, 2.0; live cases, 0.55; CL: 0.30, 0.99), and for cases dead or alive at the time of the most recent questionnaire considered in the present study (dead cases, 0.61; CL: 0.18, 2.0; live cases, 0.51; CL: 0.27, 0.95). A comparable level of consistency existed for the other childhood diseases, but their confidence limits all included the null value of 1.0.

Age at infection (table 4). For 42 of the 112 cases and 171 of the 494 controls with history of childhood measles, information on the age at measles was precise enough

TABLE 3

Estimated exposure odds ratios (EOR_{ML}) and 95% confidence limits for association between Parkinson's disease and childhood diseases: former Harvard College and University of Pennsylvania students, 1916-1978*

Disease	Cases			Controls			Unmatched		Matched†	
	Exposed	Nonexposed	Not available	Exposed	Nonexposed	Not available	EOR _{ML}	95% confidence limits	EOR _{ML}	95% confidence limits
Bacterial etiology										
Diphtheria	9	125	3	36	507	5	1.0	0.48, 2.2	1.0	0.48, 2.1
Pertussis	77	57	3	329	214	5	0.88	0.60, 1.3	0.88	0.60, 1.3
Scarlet fever	22	112	3	93	449	6	0.95	0.57, 1.6	0.84	0.49, 1.4
Rheumatic fever	4	107	26	9	441	98	1.8	0.56, 6.0	1.8	0.56, 5.7
Bacterial and/or viral etiology										
Pneumonia	21	113	3	69	474	5	1.3	0.75, 2.2	1.3	0.75, 2.2
Tonsillectomy	74	57	6	318	217	13	0.89	0.60, 1.3	0.89	0.59, 1.4
Viral etiology										
Chickenpox	76	56	5	347	194	7	0.76	0.52, 1.1	0.83	0.52, 1.3
Measles	112	20	5	494	47	7	0.53	0.31, 0.93	0.47	0.26, 0.86
Mumps	62	70	5	271	269	8	0.88	0.60, 1.3	0.82	0.54, 1.3
Influenza	32	90	15	118	376	54	1.1	0.72, 1.8	1.1	0.69, 1.8
German measles	4	4	129	11	20	517	1.8	0.38, 8.8	1.4	0.25, 7.3

* EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

† Matching on university, year of college examination, and age at examination.

MEASLES INFECTION AND PARKINSON'S DISEASE

TABLE 4

Estimated unmatched exposure odds ratios (EOR_{ML})^{} and 95% confidence limits for association between Parkinson's disease and measles, stratified by age at infection: former Harvard College and University of Pennsylvania students, 1916-1978*

Category	Cases	Controls	EOR _{ML}	95% confidence limits
No measles (reference)	20	47		
Measles at age (years)				
0-4	5	30	0.39	0.14, 1.1
5-9	24	91	0.62	0.31, 1.2
10-14	9	37	0.57	0.23, 1.4
15-19	4	13	0.72	0.21, 2.5
Measles in childhood, age not specified	64	282	0.53	0.30, 0.96
Measles, no age given	6	41	0.34	0.13, 0.92
No information on measles	5	7		

^{*} EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

to allow stratification by five-year age categories. The modal age range at measles infection was 5-9 years for both cases and controls. Sixty-four cases and 282 controls indicated that they had had measles in childhood without any more precision. Six cases and 41 controls said they had had measles but did not give any information on the time of occurrence. The reference category is composed of 20 cases and 47 controls who never had childhood measles. The exposure odds ratio varies by age and

specificity of report of age from 0.34 to 0.72. There is no clear pattern of association between age at measles and Parkinson's disease, although there is a slight trend of increasing risk of Parkinson's disease with increasing age at measles infection. This trend is not significant.

Birth cohort (table 5). Stratification by five-year birth cohort revealed a variation in the association between measles and Parkinson's disease. For two birth cohorts, that for pre-1900 and for 1920-1924, the absence of a nonexposed case leads to exposure odds ratios of infinity. The reduction in exposure odds ratio is strongest for the birth cohort 1905-1909, the exposure odds ratio being 0.20 with a two-sided *p* value of 0.001. For the following two cohorts and for the last one, exposure odds ratios are smaller than 1.0, but not significant.

Year of infection and birth cohort (table 6). We estimated the year of measles infection from the age of the subject at the time of measles if it was known. For subjects who simply indicated measles in childhood, we set the age at measles at seven years, corresponding to the modal age for subjects with a known time of measles. Changing the assumption from age seven to age three, five, or nine years did not substantially affect the results. We computed the maximum likelihood pooled exposure odds ratio

TABLE 5

Estimated birth cohort specific unmatched exposure odds ratio (EOR_{ML})^{} and 95% confidence limits for association between Parkinson's disease and measles†: former Harvard College and University of Pennsylvania students, 1916-1978*

Birth cohort	Cases			Controls			EOR _{ML}	95% confidence limits
	Exposed	Nonexposed	Not available	Exposed	Nonexposed	Not available		
Pre-1900	10	0	0	36	3	1	∞	0.15, ∞
1900-1904	32	5	0	135	12	1	0.57	0.19, 1.7
1905-1909	28	9	1	142	9	1	0.20	0.08, 0.50
1910-1914	20	3	1	89	7	0	0.52	0.13, 2.2
1915-1919	12	2	2	55	6	3	0.66	0.12, 3.7
1920-1924	7	0	1	23	8	1	∞	0.52, ∞
Post-1924	3	1	0	14	2	0	0.43	0.03, 6.5

^{*} EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

† Chi-square test for heterogeneity = 11.89, 6 df, not significant.

TABLE 6

Estimated unmatched exposure odds ratio (EOR_{ML})* of Parkinson's disease associated with measles, stratified by birth cohort and year of infection: former Harvard College and University of Pennsylvania students, 1916-1978

Birth cohort	No measles (reference)	Year of measles									Not available†	
		Pre-1900	1900-1904	1905-1909	1910-1914	1915-1919	1920-1924	1925-1929	1930-1934	Post-1934		
Pre-1900	Cases	0	1 (1)‡	3	5	1	0					0
	Controls	3	0	12 (5)	14 (3)	4	3					4
1900-1904	Cases	5	0	15 (12)	13 (11)	3						1
	Controls	12	2	59 (44)	64 (51)	6						5
1905-1909	Cases	9		0	16 (15)	9 (9)	1					3
	Controls	9		1	84 (78)	44 (37)	4					10
1910-1914	Cases	3			1	12 (7)	4 (3)	2				2
	Controls	7			2	54 (30)	24 (15)	4				5
1915-1919	Cases	2				0	9 (5)	3	0	0		2
	Controls	6				2	35 (15)	7	4	2		8
1920-1924	Cases	0					1	2	2	1		2
	Controls	8					1	9 (1)	5 (1)	1		8
Post-1924	Cases	1								2 (1)		1
	Controls	2								6 (2)		8
Birth-adjusted EOR _{ML}			0.96	0.72	0.35	0.38	0.59	1.7	1.6			
95% confidence limits			(0.09, 10.8)	(0.25, 2.1)	(0.17, 0.74)	(0.17, 0.84)	(0.21, 1.7)	(0.43, 7.2)	(0.18, 15.2)			

* EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

† Year of infection by measles unknown or no information on measles.

‡ The subgroup presented in parentheses in each cell represents the number of subjects who reported measles in childhood and are in the cell as a result of the assumption that age at measles was seven years.

adjusted for birth cohort for each of the five-year intervals for years of infection by measles from 1900 to 1934. The exposure odds ratios associated with year of infection by measles follow a U-shaped pattern. The subjects with the lowest odds ratio for Parkinson's disease are those born between 1905 and 1909, who had measles in childhood ($EOR_{ML} = 0.19$; CL: 0.07, 0.52) or early teens, before 1920 ($EOR_{ML} = 0.21$; CL: 0.07, 0.63). A cautious interpretation of the observed pattern is advisable. The adjustment procedure used in computing the exposure odds ratios for specific intervals of infection has the purpose of removing confounding by birth cohort within years of infection. It does not standardize exposure odds ratios to permit observation of a year of infection effect independent of birth cohort effects, nor is such standardization possible, since all possible comparisons of the various intervals of infection involve partially nonoverlapping cohorts and the early and late infection years include no overlap. Table 6 simply indicates that there is a significant effect associated with the 1905–1909 cohort and a significant effect associated with infection in years 1910–1919. Since the overwhelming majority of the measles of the 1905–1909 cohort occurred in 1910–1919 and approximately one-half of the 1910–1919 cases were in the 1905–1909 cohort, it is not possible to determine whether the effect is a cohort effect, a calendar time effect, or a joint cohort-time effect.

Family size (table 7). Information on number of siblings was available for 133 of 137 cases and 543 of 548 controls. No confounding by family size is present in this data set; the distributions of siblings for cases and controls are similar, leading to identical crude and unconfounded exposure odds ratios. Stratification by family size shows a strong reduction in the relative risk of Parkinson's disease associated with childhood measles for only children. An increased risk associated with measles for subjects with one sibling is based on only

one nonexposed case. For subjects having at least two siblings, the exposure odds ratio associated with measles is low for families with 2–4 siblings but rises for families with over four siblings. The instability of the results prevents any firm conclusion with regard to effect modification by number of siblings.

Other childhood viral diseases (table 8)

In order to explore a potential modification of the relation between measles and Parkinson's disease, stratification was done by the presence or absence of the other two viral diseases for which we had sufficient information, chickenpox and mumps. The exposure odds ratio for measles is remarkably stable, approximately 0.5, whether the subject had only measles or measles and one or two of the other diseases.

Influenza

Influenza does not appear as a risk factor for Parkinson's disease. Stratification by birth cohort shows an increase in exposure odds ratio for the cohort born prior to 1900 and the 1910–1914 and 1915–1919 birth cohorts, but the increase is not significant (table 9). Information on influenza was not collected for subjects entering college after 1939 and, as a consequence, we do not have information for most of the subjects born in 1920 or later. Stratification by age at infection shows an exposure odds ratio of about one for all categories (table 10). Numbers were too small to allow for cross-stratification by birth cohort and year of infection by influenza.

Multivariate analysis (table 11)

A matched logistic regression analysis was performed to simultaneously study associations with several childhood diseases (chickenpox, measles, mumps, influenza, pertussis, diphtheria, pneumonia, scarlet fever, and tonsillectomy), number of siblings, and smoking and diastolic blood pressure at the time of college entrance. This analysis was mainly done to evaluate po-

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TABLE 7

Estimated unmatched exposure odds ratios (EOR_{ML})^{} and 95% confidence limits for association between Parkinson's disease and measles, stratified by family size: former Harvard College and University of Pennsylvania students, 1916-1978*

No. of siblings	Cases			Controls			EOR _{ML}	95% confidence limits
	Exposed	Nonexposed	Not available	Exposed	Nonexposed	Not available		
0	10	4	1	55	5	2	0.23	0.06, 0.92
1	31	1	1	138	12	2	2.7	0.36, 20.0
2-4	58	13	2	248	22	1	0.40	0.19, 0.82
>4	10	2	0	49	8	1	0.82	0.15, 4.5

* EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

tential confounding by several factors simultaneously. Diseases were introduced as dichotomous variables, as was smoking at the time of college (ever- vs. never-smoker). Diastolic blood pressure was treated as a continuous variable. Only subjects for whom we had complete information on all the variables of interest were included in this part of the analysis. We have 103 sets with a variable matching-ratio from one to four. The crude exposure odds ratio for measles, given by the matched logistic regression is 0.37 with confidence limits of 0.19, 0.71. After controlling for the other childhood diseases, smoking, and blood pressure, the adjusted exposure odds ratio for measles is still 0.40, with confidence limits 0.20, 0.80, and the two-sided p value is 0.009. The value of the coefficient for measles and its confidence limits are essentially unaffected by the introduction of the other variables in the model.

DISCUSSION

The major finding of this study is a reduced exposure odds ratio of Parkinson's disease for subjects who had a history of measles at college entrance.

With prevalent cases ascertained at the time of a morbidity questionnaire, the exposure odds ratio is an estimate of the prevalence odds ratio, which is approximately equal to the incidence density ratio if one assumes that the average duration of disease is the same for exposed and non-exposed subjects, that mortality from all

causes is the same for exposed and nonexposed, and that the disease is rare in all groups. With prevalent cases ascertained at the time of a morbidity questionnaire taken together with all deceased cases, the exposure odds ratio is an estimate of a cumulative incidence odds ratio, relating all cases to all surviving noncases. The cumulative incidence odds ratio is approximately equal to the incidence density ratio under the same assumptions as above with regard to all-cause mortality and rare disease. No assumption relative to duration is required in its interpretation. In this study, the median age at onset of disease was 61 years for subjects who had a history of measles and 59.5 years for those who had a negative or unknown history. The median age at death was 69 years for both groups. The duration of disease did not differ significantly between exposed and nonexposed cases. In addition, we believe that it is unlikely that there was a selective loss of subjects through death differential for those who had childhood diseases and those who did not. Stratification by life status, at the time of ascertainment or at the time of the last questionnaire, as well as stratification by year of diagnosis did not introduce any substantial modification of the results. Therefore, the exposure odds ratios presented in this paper can be considered estimates of the incidence density ratios.

The following discussion explores potential explanations for the observed result.

Misclassification of disease and exposure status

Inclusion of non-Parkinson's disease among cases or of cases among controls, as well as nondifferential misclassification of measles for cases and controls, would bias the measure of association between exposure and disease toward the null value.

False positive diagnoses of both measles and Parkinson's disease are unlikely. False negative diagnoses of either may be common, but the circumstances that could lead to differential misclassification seem unlikely. The exposure status, childhood infection, was recorded at college entrance and could not be influenced by the subsequent presence of Parkinson's disease. The outcome status, Parkinson's disease, was almost certainly diagnosed without reference to the fact of prior exposure. The independent recording of exposure and outcome, abstracted from the same documents, used identical procedures for cases and controls. Exposure information was missing for 23 of 160 potential cases. This could potentially lead to selection bias. To evaluate this, we can consider the hypothetical measles experience for these 23 subjects most unfavorable to our result. If we consider that all 23 potential cases for whom we do not have information on childhood diseases had measles and that their 92 matched controls had identical exposure frequencies to those of the controls of cases with data on childhood diseases, we still get an exposure odds ratio of 0.64 (CL: 0.37, 1.1).

Misclassification of the age at infection with measles is possible. A greater problem with this variable was the absence of information. Fifty-seven per cent of subjects with a positive history of measles failed to give the age at infection. This proportion was the same for cases and controls. We found no significant association of Parkinson's disease with age at infection (table 4). While it is possible that the large amount of missing information on this variable may have concealed a significant relation, this deficiency cannot logically have affected

TABLE 8
Estimated unmatched exposure odds ratio (EOR_{ML})* and 95% confidence limits for association between Parkinson's disease and measles, stratified by chickenpox and mumps: former Harvard College and University of Pennsylvania students, 1916-1978

Disease category	Cases				Controls			EOR _{ML}	95% confidence limits
	Exposed	Nonexposed	Not available	Exposed	Nonexposed	Not available			
No chickenpox, no mumps	29	10	1	95	18	0	0.55	0.23, 1.3	
Chickenpox, no mumps	25	4	1	142	12	1	0.53	0.16, 1.7	
No chickenpox, mumps	13	3	0	72	8	0	0.48	0.12, 2.0	
Chickenpox, mumps	42	3	0	181	7	2	0.54	0.14, 2.1	

* EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

TABLE 9

Estimated unmatched exposure odds ratio (EOR_{ML})^{} and 95% confidence limits for association between Parkinson's disease and influenza, stratified by birth cohort: former Harvard College and University of Pennsylvania students, 1916-1978*

Birth cohort	Cases			Controls			EOR _{ML}	95% confidence limits
	Exposed	Nonexposed	Not available	Exposed	Nonexposed	Not available		
Pre-1900	1	9	0	1	39	0	4.3	0.30, 63.3
1900-1904	7	30	0	30	117	1	0.91	0.36, 2.3
1905-1909	11	27	0	53	98	1	0.75	0.35, 1.6
1910-1914	9	14	1	29	67	0	1.5	0.58, 3.8
1915-1919	3	8	5	5	47	12	3.5	0.74, 16.7

^{*} EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

TABLE 10

Estimated unmatched exposure odds ratio (EOR_{ML})^{} and 95% confidence limits for association between Parkinson's disease and influenza, stratified by category of age at infection: former Harvard College and University of Pennsylvania students, 1916-1978*

Category	Cases	Controls	EOR _{ML}	95% confidence limits
No influenza (reference)	90	376		
Influenza at age (years)				
0-9	5	20	1.0	0.38, 2.9
10-14	14	48	1.2	0.64, 2.3
15-24	8	32	1.0	0.47, 2.3
Influenza, no age given	5	18	1.2	0.42, 3.2
No information on influenza	15	54	1.2	0.63, 2.2

^{*} EOR_{ML}, maximum likelihood estimate of the exposure odds ratio.

TABLE 11

Matched^{} logistic[†] exposure odds ratios (EOR_{ML}) and 95% confidence limits for association between Parkinson's disease and selected childhood diseases: former Harvard College and University of Pennsylvania students, 1916-1978*

Disease	EOR _{ML}	95% confidence limits
Diphtheria	0.76	0.29, 2.0
Pertussis	0.79	0.49, 1.3
Scarlet fever	1.1	0.62, 2.0
Pneumonia	1.2	0.65, 2.2
Tonsillectomy	0.86	0.53, 1.4
Chickenpox	0.86	0.52, 1.4
Measles	0.40	0.20, 0.80
Mumps	0.91	0.54, 1.5
Influenza	1.1	0.79, 1.7

^{*} Matching on university, year of college examination, and age at examination.

[†] Logistic model including diphtheria, pertussis, scarlet fever, pneumonia, tonsillectomy, chickenpox, measles, mumps, influenza, number of siblings, smoking, and diastolic blood pressure.

our principal results. As noted in our discussion of year of infection and birth cohort, the large effect associated with measles in 1910-1919 is equally well explained as a birth cohort effect for the 1905-1909 cohort or as a year of infection effect for 1910-1919. The interpretation does not depend on the assignment of year of infection within cohorts.

Confounding

Potential confounding of diagnosis of Parkinson's disease by age and institution was eliminated by matching. Confounding by social class could not be totally assessed.

No information on parental income and education was available for most of the subjects. Nevertheless, all cases and controls came from a rather uniform population. They all attended one of two private northeastern United States universities in the first half of this century, at a time when financial aid to lower social classes was more limited. Their families' social position was likely to be middle or upper class. The effects of history of childhood diseases other than measles and of diastolic blood pressure and smoking at the time of college entrance have been accounted for in the

matched multivariate analysis. Other risk factors for Parkinson's disease, such as exposure to drugs, arteriosclerosis, and smoking later in life, were not considered in this analysis. Such later occurring events would unlikely confound the relationship between measles and Parkinson's disease, although they might modify an effect. Desirable, although not available, would be information on exposure to pets, with possible cross-reaction between measles virus and viruses of canine distemper and rinderpest of cattle.

Interpretation

The idea of a relation between measles virus and a neurologic disease is not a surprising notion. Encephalomyelitis is the most serious acute complication of measles infection. The encephalitis, characterized by pathologic features reminiscent of allergic encephalitis, could be due to a hypersensitivity response either to the measles virus or to virus-altered host tissue (autoimmune reaction) (20). Measles virus has also been implicated or suspected in at least two chronic neurologic diseases: subacute sclerosing panencephalitis (21-25) and multiple sclerosis (26, 27).

In this study, the findings suggest a protective, rather than a detrimental, effect of measles infection in childhood. Four potential explanations will be presented and discussed.

First, no history of measles at the time of college entrance could refer to subjects who will develop measles in adulthood. Such a late infection could be a risk factor for Parkinson's disease. The proportion of children affected by measles encephalitis was found in 1955 to increase with increasing age at measles infection (28). A similar mechanism could play a role in Parkinson's disease. The late measles theory would be compatible with the finding of high risk in children without siblings and with the general pattern of a relative lack of common viral childhood diseases among the cases. The theory would also be compatible with

the trend by age at infection suggested in table 4, although those data are very uncertain, as discussed above.

Second, the absence of a history of measles infection could reflect either true absence of measles infection or an atypical clinically inapparent measles infection, such as one occurring very early in life, at the time of protection by maternal antibodies. If this were the case, the negative association between a reported measles infection and Parkinson's disease would be more likely to be observed in children with older siblings potentially exposed to earlier measles in the household than in only children. This is not observed in this study; although the family size-specific exposure odds ratios are unstable, only children seem to be the ones at higher risk of Parkinson's disease if they did not report a history of measles infection.

Third, the increased risk of Parkinson's disease for subjects who did not have measles could in part be explained by an increase in risk among subjects who were in general protected from childhood infections. In particular, a negative history of measles could indicate an associated absence of infection by influenza before 1918. This would make subjects more susceptible to adulthood influenza during the 1918 influenza epidemic, and this could represent a risk factor for Parkinson's disease (4, 6). This theory is compatible with the increase in risk in children without siblings and with the finding that cases have had fewer exposures than controls to most viral childhood diseases. Unfortunately, we could not identify in this data set, the subjects who had the Spanish flu. The question on influenza in the college medical evaluation did not specifically ask for influenza during the epidemic. The occurrence of the disease was too restricted in time (of the order of one year) to enable us to estimate with sufficient precision who had the disease in 1918, based on information on age at infection. No information was available about later occurring influenza after the college evalu-

ation. We did not attempt to inquire now into a history of influenza in 1918 because we felt any response to such a question would be potentially too subject to influence by the present knowledge of Parkinson's disease to be interpretable. Three of the validated cases, all with an early onset of Parkinson's disease, were categorized as postencephalitic by the physicians who validated the diagnosis, and, for one case, the physician mentioned influenza in 1918.

Fourth, there may be a truly protective effect of measles infection, and a possible interaction with the 1918 influenza virus. One can speculate that infection by the influenza virus in 1918 or by a mutant virus in the following years could lead to clinically apparent encephalitis in some cases but could also remain subclinical. Pathologic changes would include various degrees of infiltration of the central nervous system by lymphocytes and cytotoxic reactions. The involvement of the brain could follow a slowly progressive autoimmune pattern, responsible in the following decades for Parkinson's disease. Subjects who had measles prior to the influenza and encephalitis epidemics may have had a temporarily reduced or altered function of some T cell subsets which might otherwise be associated with or responsible for injury of the central nervous system. It was noted in 1918 that influenza in subjects under the age of 13 years was mild. More recent serologic studies during subsequent epidemics have shown a high frequency of clinically inapparent infections in young people (29). In 1932, Hedrich (30), in an evaluation of the monthly estimates of the child population susceptible to measles in Baltimore, Maryland from 1900 to 1931, mentioned a peculiar behavior of the curve of proportion of children susceptible to measles, reaching the lowest point in three decades in the spring of 1918 during a measles epidemic. The coincidence with the beginning of the influenza epidemic was already noted (30).

The results presented in this study are in agreement with those of Kessler (14, 15),

who found that cases of Parkinson's disease reported a history of measles as well as other common viral diseases less frequently than controls. A study of antibodies to measles in serum and cerebrospinal fluid comparing cases of idiopathic Parkinson's disease to nonparkinsonian neurologic and medical patients showed a significantly lower mean titer in sera of patients with Parkinson's disease than in those of controls (31). This was not confirmed in another study, in which no difference in geometric titer was found (32). Before drawing any firm inference from the data presented, it will be necessary to await replication of the results in different populations. It would also be of interest to try to confirm the physiopathologic mechanism of a possible measles-influenza interaction with the help of experimental studies. At this time, no argument is available for allowing a definite choice among the four hypotheses stated above. The interest in such a question is not solely historical. Since 1963, the United States has adopted a policy of immunization against measles. Live attenuated virus vaccines are used, and it is known that the type of immunity conferred by the vaccine is less durable and different from the immunity conferred by the naturally occurring disease (33). It is not clear at this time whether one would predict more or less protection from Parkinson's disease with a measles vaccination program. Brain reactivity to the vaccine should be carefully assessed, as well as interaction with various mutant strains of influenza virus.

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Exhibit L

Open forum

Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy[☆]

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Abstract

To investigate the association between non-Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL), and exposure to childhood diseases, we analyzed an Italian case-control study that included 225 histologically-confirmed incident cases of NHL, 62 HL cases, and 504 controls. After adjusting for confounding factors, all examined childhood diseases were negatively associated with HL. Measles was negatively associated with NHL, particularly follicular B-cell NHL. Our findings provide additional support to the hypothesis that infections by most common childhood pathogens may protect against HL or, at least, be correlated with some other early exposure, which may lower the risk of HL in adulthood. In addition, our study shows that measles may provide a protective effect against NHL.

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Keywords: Non-Hodgkin lymphoma (NHL); Hodgkin lymphoma (HL); Childhood diseases; Case-control study; Immunostimulation

1. Introduction

In most developed countries, Hodgkin lymphoma (HL) incidence has been stable, while that of non-Hodgkin lymphoma (NHL) has doubled over the past two decades [1,2]. The risk for some lymphomas is known to increase following exposure to certain viral or bacterial infections [2,3]. The only virus, thus far, established to be causally related to HL is the Epstein-Barr virus (EBV), with an approximately 40% attributable fraction [1,4] and the demonstration

that EBV genomes were present and expressed in the HD tumor cells (Reed-Sternberg cells) of a proportion of cases provided an important new understanding of the biology of the disease [5,6]. For several infectious agents (HIV, HHV8, HTLV, HCV, and *Helicobacter pylori*) [2,7–16], on the contrary, exist only indirect evidence of positive association due to the capacity to elude the immune system [17]. The childhood infections may have the opposite (protective) effect on lymphoma risk because of a different age of infection and/or less severe infections. In fact since 1988 some studies reported a potential protective effect of measles and other childhood diseases for lymphoma and multiple myeloma [7–9,18]. However, the etiology of most lymphomas is still unknown.

To further explore this topic, we investigated the potential association between NHL, HL, and a history of childhood diseases and mononucleosis using data from an Italian case-control study on lymphomas carried out in the province of

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Pordenone, northeast Italy, and in the city of Naples, southern Italy [13,14].

2. Material and methods

Between January 1999 and July 2002, we conducted a hospital-based case-control study in the province of Pordenone (northeast Italy) and in Naples (southern Italy). Details on study design are described elsewhere [13,14]. Briefly, the present report looks at 225 histologically-confirmed incident NHL cases and 62 HL cases, aged 18 years or more. Controls were 504 inpatients admitted to the same hospitals as those with the lymphomas for a wide spectrum of acute conditions. Specifically excluded from the control group were patients whose hospital admission was the result of malignant diseases, conditions related to alcohol and tobacco consumption, or hepatitis viruses. Hematological, allergic, and autoimmune diseases were also excluded. Co morbidity for the diseases listed above was not, however, a criterion for exclusion.

Histological specimens were classified according to the International Classification of Diseases for Oncology, which was updated to include categories in the Revised European-

American Lymphoma (REAL)/World Health Organization (WHO) classification [19].

All cases and controls were HIV-negative at HIV test, which was part of their routine management.

The interviews were conducted by means of a structured questionnaire, covering socio-demographic indicators, personal characteristics, and habits. In addition, the questionnaire included medical history and age at onset of the primary childhood infections. Cases were not individually matched to controls but they were comparable according to age and gender.

Adjusted ORs and corresponding 95% CIs were calculated by means of unconditional multiple logistic regression, including age (in 5-year groups plus a term for age as a continuous variable), gender, center, education, and place of birth. Individuals who reported mononucleosis and childhood diseases were compared with those who did not have these diseases.

3. Results

Education was negatively associated with HL (OR=0.4, in the highest tertile compared to the lowest, 95% CI:

Table 1

Distribution of 225 cases of non-Hodgkin lymphoma (NHL), 62 cases of Hodgkin lymphoma (HL), and 504 controls, odds ratios (OR) and corresponding 95% confidence intervals (CI)^a by selected socio-demographic factors (Italy, 1999–2002)

	Controls		NHL		OR	(95% CI)	HL		OR	(95% CI)
	No.	(%)	No.	(%)			No.	(%)		
Gender										
Males	341	(67.7)	120	(53.3)			33	(53.2)		
Females	163	(32.3)	105	(46.7)			29	(46.8)		
Age (years)										
<45	104	(20.6)	47	(20.9)			50	(80.7)		
45–64	177	(35.1)	107	(47.6)			10	(16.1)		
≥65	223	(44.3)	71	(31.6)			2	(3.2)		
Study center										
Aviano/Pordenone	280	(55.6)	127	(56.4)			37	(59.7)		
Naples	224	(44.4)	98	(43.6)			25	(40.3)		
Education (years)										
<7	251	(49.8)	97	(43.1)	1 ^c		12	(19.4)	1 ^c	
7–11	127	(25.2)	69	(30.7)	1.4	(0.9–2.1)	27	(43.6)	0.7	(0.3–1.8)
≥12	126	(25.0)	59	(26.2)	1.2	(0.8–1.8)	23	(37.1)	0.4	(0.1–1.0)
Place of birth										
North	248	(49.2)	98	(43.6)	1 ^c		23	(37.1)	1 ^c	
South	256	(50.8)	127	(56.4)	2.1	(1.2–3.5)	39	(62.9)	1.3	(0.5–3.3)
Younger siblings^b										
0	164	(32.5)	78	(34.7)	1 ^c		24	(38.7)	1 ^c	
1–2	230	(45.6)	97	(43.1)	0.9	(0.6–1.3)	28	(45.2)	0.9	(0.5–1.9)
≥3	110	(21.8)	50	(22.2)	1.1	(0.7–1.7)	10	(16.1)	1.4	(0.5–3.7)
Older siblings^b										
0	162	(32.1)	82	(36.4)	1 ^c		20	(36.4)	1 ^c	
1–2	226	(44.8)	106	(47.1)	0.9	(0.6–1.3)	26	(41.9)	0.8	(0.4–1.6)
≥3	116	(23.0)	37	(16.4)	0.6	(0.4–1.0)	16	(25.8)	1.2	(0.5–2.9)

^a Estimated from unconditional logistic regression adjusted for gender, age, center, education, and place of birth when appropriate.

^b The sum does not add up to the total because of some missing value.

^c Reference category.

0.1–1.0), but not with NHL (OR = 1.2; 95% CI: 0.7–1.8); while place of birth (Southern Italy versus Northern Italy) demonstrated an association only to NHL risk (OR = 2.1; 95% CI: 1.2–3.6). No difference emerged between cases (both NHL and HL) and controls based on number of younger siblings. However, a negative association (OR = 0.6; 95% CI: 0.4–1.0) did emerge for NHL only when there were three or more older siblings (Table 1).

Table 2 shows the relationship between lymphomas and a history of mononucleosis and/or childhood diseases. NHL showed a negative association with measles (OR = 0.6, 95% CI: 0.5–0.9); other childhood infections showed no association with NHL.

HL was negatively associated with all considered childhood diseases (Table 2). The significant ORs were for measles (OR 0.5, 95% CI: 0.2–0.7) and chickenpox (OR 0.5, 95% CI: 0.2–0.9), border-line values were found for parotitis (OR 0.6), rubella (OR 0.5), pertussis (OR 0.5), and scarlet fever (OR 0.2).

The OR among individuals who reported a history of three or more childhood diseases was 0.6 (95% CI: 0.4–1.0) for

NHL and 0.2 (95% CI: 0.1–0.6) for HL, when compared to subjects who reported no disease. Findings were similar when analysis were conducted separately for cases and controls below or above 45 years of age (data not shown). The odds ratios for number of childhood infections does not decrease with increasing number and does not substantially differ from the odds ratio from measles infection alone.

In Table 3 the risk of childhood diseases for two histological subtypes of NHL, in particular the negative associations found with measles exposure tended to be stronger for follicular B-cell NHL (OR 0.4, 95% CI: 0.2–0.8) than for diffuse large B-cell. Heterogeneity by histological subtype, however, did not demonstrate any statistical significance.

The inverse association between childhood diseases and risk of HL was restricted to nodular sclerosis HL (OR 0.3, 95% CI: 0.1–0.7). However, there were few cases of histological subtype other than nodular sclerosis (*n* = 19), limiting the power to detect any association with other HL subtypes (data not shown).

Table 2

Odds ratios (OR)^a and 95% confidence intervals (CI) for non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma (HL) according to childhood infections (Italy, 1999–2002)

	Controls		NHL		OR	(95% CI)	HL		OR	(95% CI)
	No.	(%)	No.	(%)			No.	(%)		
Viral infections										
Infectious mononucleosis										
Never	501	(99.4)	223	(99.1)	1 ^b		60	(96.8)	1 ^b	
Ever	3	(0.6)	2	(0.9)	1.5	(0.2–9.4)	2	(3.2)	1.9	(0.2–16.4)
Parotitis (mumps)										
Never	269	(53.4)	117	(52.0)	1 ^b		35	(56.5)	1 ^b	
Ever	235	(46.6)	108	(48.0)	0.9	(0.7–1.3)	27	(43.6)	0.5	(0.3–1.0)
Measles										
Never	163	(32.3)	84	(37.3)	1 ^b		25	(40.3)	1 ^b	
Ever	341	(67.7)	141	(62.7)	0.6	(0.5–0.9)	37	(59.7)	0.3	(0.2–0.7)
Rubella (German measles)										
Never	391	(77.6)	161	(71.6)	1 ^b		46	(74.2)	1 ^b	
Ever	113	(22.4)	64	(28.4)	1.1	(0.8–1.7)	16	(25.8)	0.5	(0.2–1.0)
Chickenpox										
Never	277	(55.0)	128	(56.9)	1 ^b		30	(48.4)	1 ^b	
Ever	227	(45.0)	97	(43.1)	0.9	(0.6–1.2)	32	(51.6)	0.5	(0.2–0.9)
Bacterial infections										
Pertussis (whooping-cough)										
Never	377	(74.8)	174	(77.3)	1 ^b		48	(77.4)	1 ^b	
Ever	127	(25.2)	51	(22.7)	0.7	(0.5–1.1)	14	(22.6)	0.5	(0.2–1.0)
Scarlet fever										
Never	455	(90.3)	198	(88.0)	1 ^b		60	(96.8)	1 ^b	
Ever	49	(9.7)	27	(12.0)	1.2	(0.7–2.0)	2	(3.2)	0.2	(0.0–1.0)
Number of childhood infections										
0	106	(21.0)	59	(26.2)	1 ^b		13	(21.0)	1 ^b	
1–2	210	(41.7)	76	(33.8)	0.5	(0.3–0.8)	21	(33.9)	0.2	(0.1–0.6)
≥3	188	(37.3)	90	(40.0)	0.6	(0.4–1.0)	28	(45.2)	0.2	(0.1–0.5)

^a Estimates from unconditional logistic regression equations, including terms for center, age, gender and years of education, and place of birth.

^b Reference category.

Table 3

Odds ratios (OR)^a and 95% confidence intervals (CI) for major non-Hodgkin lymphoma (NHL) subtypes in relation to history of childhood infections (Italy, 1999–2002)

Risk factors	Controls (No.)	Non-Hodgkin lymphomas								
		Follicular B-cell (36 cases)			Diffuse large B-cell (112 cases)			Other subtypes (77 cases)		
		No.	OR	(95% CI)	No.	OR	(95% CI)	No.	OR	(95% CI)
Viral infections										
Parotitis (mumps)										
Never	269	22	1 ^b		53	1 ^b		42	1 ^b	
Ever	235	14	0.6	(0.3–1.3)	59	1.1	(0.7–1.7)	35	0.8	(0.5–1.4)
Measles										
Never	163	17	1 ^b		39	1 ^b		28	1 ^b	
Ever	341	19	0.4	(0.2–0.8)	73	0.7	(0.5–1.2)	49	0.7	(0.4–1.1)
Rubella (German measles)										
Never	391	28	1 ^b		77	1 ^b		56	1 ^b	
Ever	113	8	0.8	(0.3–1.9)	35	1.3	(0.8–2.1)	21	1.2	(0.6–2.2)
Chickenpox										
Never	277	20	1 ^b		64	1 ^b		44	1 ^b	
Ever	227	16	0.9	(0.4–1.9)	48	0.8	(0.5–1.3)	33	0.9	(0.5–1.5)
Bacterial infections										
Pertussis (whooping-cough)										
Never	377	31	1 ^b		82	1 ^b		61	1 ^b	
Ever	127	5	0.4	(0.1–1.1)	30	0.8	(0.5–1.4)	16	0.7	(0.4–1.3)
Scarlet fever										
Never	455	35	1 ^b		96	1 ^b		67	1 ^b	
Ever	49	1	0.3	(0.0–2.1)	16	1.3	(0.7–2.4)	10	1.4	(0.6–3.0)

^a Estimates from unconditional logistic regression equations, including terms for center, age, gender, years of education, and place of birth.

^b Reference category.

4. Discussion

The etiological agents (viruses and bacteria) involved in the examined diseases are very different. Several studies have reported a positive association between mononucleosis and risk of HL, but so far present, the mechanisms through which other childhood infections in general may protect against HL and possibly NHL are unknown [1,2,20]. Early infection may promote the development of the immune system (particularly cell-mediated, Th1-type immunity), which may explain why young-adulthood infection with EBV increases the risk of HL, but earlier infection is inversely associated with the risk [1,4,5].

For NHL, some studies have shown a negative association provided by certain childhood viral infections (e.g. measles and chicken pox) and certain childhood bacterial infections (e.g. pertussis) [7,21]. Our study showed a protective effect only by measles; this result agrees with other studies which reported that attenuated measles virus (MV) has therapeutic potential as a replicating oncolysis virus in models of non-Hodgkin lymphoma [22,23]. Moreover, a recent study reported that in the presence of an intact immune system, therapy with repleting MV stimulates a strong neutrophil anti-tumor response, which can be cytokine-enhanced to improve oncolysis [24]. In addition, there is already a study from 1981, which reported a regression of Hodgkin's disease after measles [25], while a recent study reported

a negative association between lymphoma and measles [26].

For HL, our results agree with the hypothesis that certain childhood infections may provide a protective effect with subsequent immunostimulation on HL [20,27]. Indirect support for this hypothesis is further provided by studies which show that having 1–2, or even 3 or more siblings, a surrogate marker of earlier exposure to common childhood pathogens, is inversely related to HL risk [28].

No change in relative risk was seen for age at onset of childhood diseases among siblings either HL or NHL. Perhaps, this may be due to the difficulty in establishing a specific age-at-onset time-frame, as the age the children are introduced to school varies, profoundly affecting disease transmission.

Our findings are consistent with the oncogenesis (oncogenic mechanism) of different lymphomas: both HL and the most frequent NHL subtypes, i.e. follicular cell and diffuse large B-cell lymphomas, derive from antigen-exposed B-cells which undergo neoplastic transformation within the germinal centers (GC) of lymph nodes or secondary lymphoid organs [29]. In particular, the process of somatic hyper mutation of immunoglobulin variable region genes, while generating antibody diversity and increasing antigen affinity, creates a 'permissive' setting for lymphoma genesis-associated chromosomal translocations and mutations to occur. Such process is mediated by B-cells interaction with T-lymphocytes [29].

Thus, B-cell lymphoma genesis is strictly dependent on biologic features of both target B-lymphocytes and T-cell subsets controlling their physiologic development. While HL arises from preapoptotic ‘crippled’ B-cells, rescued by the transforming event within the GC, most B-NHL derive from cells undergone favorable (ongoing) mutations of immunoglobulin genes [29,30]. In addition, while bystander T-cells have been shown to favorably affect prognosis of B-NHL [31], several evidences indicate that surrounding T-cells may promote tumor cells survival in HL [30]. Therefore HL and NHL display consistent differences in terms of both transformation-targeted cells and tumor cells interplay with normal T-cell populations. Common childhood infections are associated with the development of both humoral and long-lasting cell-mediated immune responses, with virus-specific T-cells persisting more than 11 years after exposure in the case of measles [32]. Virus-specific B- and T-cells may then exert a divergent role in lymphoma genesis, by creating a non-permissive immune microenvironment for HL development from ‘crippled’ B-cell progenitors while turning less efficient in controlling the expansion of NHL B-cells undergone favorable immunoglobulin gene mutations.

Due to the limits of our study, notably the reliance on the self-reported history of childhood infections and infectious mononucleosis, our results should be viewed with caution. In particular, the specific association of only measles with NHL could be due entirely to chance, or it could be due to the lack of statistical power to detect associations with other childhood infections. No clear reason emerges to expect higher prevalence of childhood infections among controls. As specified in Ref. [13], controls were admitted to the hospital for trauma (27%), for non-traumatic orthopaedic diseases (23%), for acute surgical conditions (22%), for eye diseases (14%), and for a variety of other illnesses (14%). All these conditions are apparently weekly related to childhood infections occurred several decades before. A recall bias for cases and controls is also possible, but highly unlikely, as the possible association between childhood diseases and lymphoma risk was not of public domain, and all interviews were performed in a similar hospital setting. Unfortunately, in Italy there are few studies of prevalence for adults of all these childhood infections. Furthermore the prevalence of childhood infections among our hospitalized controls is overlapping to Italian prevalence [33].

5. Conclusions

Our findings provide additional support to the hypothesis that infections by most common childhood pathogens may protect against HL [4,34] or, at least, be correlated with some other early exposure, which may lower the risk of HL in adulthood. In addition, our study is one of the few study to provide evidence that measles may provide a protective effect against NHL [22,23,25,35], particularly follicular B-cell lymphomas, which is in line with studies reporting that patients

with low-grade B-cell NHL had more benefit from the induction of the tumor-specific anti-idiopathic immune response [36]. Our results are still in agreement with other studies and are consistent with the hypothesis of an immunogenic stimulation provided by some childhood diseases [20,26].

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Exhibit M

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Febrile infectious childhood diseases in the history of cancer patients and matched controls

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Abstract — The present study was designed to investigate the hypothesis that febrile infectious childhood diseases (FICDs) are associated with a lower cancer risk in adulthood, since biographical considerations are of great importance in anthroposophic medicine. Cancer patients and control patients of 35 anthroposophic general practitioners in Switzerland were matched with respect to gender, age and physician. All patients completed a questionnaire on their FICD. We collected 424 cases; of these we could analyze 379 matched pairs. The study consistently revealed a lower cancer risk for patients with a history of FICD. The strongest associations were found between patients with non-breast cancers and rubella respectively chickenpox. A strong association was also found with the overall number of FICD both 'classical' (measles, mumps, rubella, pertussis, scarlet-fever and chickenpox) and 'other'. None of these associations was apparent for patients with breast cancer. Unexpectedly, we found that cancer was diagnosed significantly earlier in life in cancer patients with a history of FICD compared to those without FICD. Our retrospective study showed a significant association between FICD and the risk of developing cancer. The number of FICD decreased the cancer risk, in particular for non-breast cancers. The relationship with tumor site seems to be important also, but can only be addressed in a larger study.

Introduction

The association of febrile infectious diseases and cancer was postulated a long time ago. As early as 1910 Schmidt (1) found, of 241 cancer patients, only 109 with a history of FICD. Schmidt distinguished between a 'diathesis inflammatoria' and an 'afebrile diathesis'. The latter was associated with a higher cancer risk. Schmidt's findings were confirmed later by some studies based on anamnestic inquiries of cancer patients only (c.f. Braunstein (2), Ungar (3), Kofler and Hussarek (4) and Schulz (5)). Other publications are based on case-control studies. Engel (6,7)

found that, of 300 cancer patients, 113 had no FICD, compared to 300 controls with only 16 without FICD. This association holds true also when corrected for age. Sinek (8) found similar results in a study based on 232 cancer patients and 2444 controls. Witzel (9) and Remy et al (10) focused on the occurrence of febrile diseases within 5–10 years prior to the first cancer diagnosis and confirmed the same association. Three case-control studies by West (11), Wynder et al (12) and Newhouse et al (13) report a decreased cancer risk for women with a FICD history.

In contrast, in a critical review of previously published data, Abel et al (14) concluded that, 'The

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early studies, which gave impressive relative risks or established associations between childhood infections and cancer in adults, had severe deficiencies in design and analysis'. Abel therefore initiated an extensive case-control study of 255 patients with cancer of stomach, colon, rectum, breast or ovary and 485 controls, using a lengthy standard questionnaire containing 76 questions. A negative association was shown between a history of common cold or gastroenteritis within 5–10 years prior to the interview and the risk of developing cancer. In regard to FICD, Abel found slightly reduced odds ratios relative to the population controls. The *P*-value was 5 to 10% for chickenpox and pertussis.

The aim of our case-control study was to re-evaluate the hypothesis by focusing on FICD and considering the respective age of FICD and the time of cancer diagnosis. To analyse a particular, presumably more homogeneous population we considered patients of anthroposophic general practitioners.

Method

The study was designed as a matched case-control study based on the patients of anthroposophic general practitioners of Switzerland. Of the 50 anthroposophic general practitioners in Switzerland, 15 declined to participate because of lack of time. We included all of the remaining 35 practitioners in order to reduce observer bias, to have a large number of practitioners, and to obtain a sufficiently large number of cases.

Cases

All patients with a diagnosis of carcinoma (malignant solid epithelial tumor) who for any reason were seen in the office of a participating practitioner between 1 June 1993 and 31 January 1994 were accepted as cases. A limit of 20 patients per office was chosen in order to avoid any preponderance of a particular office and to limit the amount of work for one doctor. We collected 424 cases; 410 were accepted; 14 cases whose diagnosis did not meet the criteria (4 lymphomas, 2 myelomas, 4 sarcomas, 1 leukemia, 1 glioblastoma, 2 men with a breast cancer) had to be eliminated. A short questionnaire regarding the history of FICD was filled out by the patients without the doctor's help.

Controls

For each case, a control person of the same gender, the same age group (± 3 years) and of the same practitioner, but without a diagnosis of malignancy,

was drawn randomly from the alphabetical patient register in the practitioner's office. As cases and controls were drawn from the same register, it seemed to be acceptable to assume that their respective places of residence were close to each other. Control patients were contacted either in a subsequent consultation, by phone or by mail and were asked to fill out the same questionnaire. Nine controls (2.2%) had to be eliminated because of unsuitable matching. Eighteen controls (4.4%) did not return the questionnaire, and 4 questionnaires contained insufficient data, leaving a final total of 379 matched pairs (93%). For the analysis of the cases, we used the information of all relevant patients.

Questionnaire

Cases and controls received the questionnaire knowing neither the aim of the study nor their group affiliation. Information was collected about gender, age at interrogation, number of brothers and sisters, a possible history of 'classical' FICD (measles, mumps, rubella, chickenpox, pertussis, scarlet fever) including the corresponding age, the frequency of 'other' FICDs (fever $> 39^{\circ}\text{C}$) up to the age of 21, and some other questions of minor importance. It is obvious that it may be difficult to remember the FICD, in particular for older patients. However, we believe that cases and controls remember their FICD in the same way. Because of matching and random selection this should not influence our analysis negatively.

To answer the questions about FICD, the patients chose among 'yes', 'uncertain yes', 'uncertain no' and 'no'. (By giving 4 options, we wanted to avoid a tendency to pick the middle choice in a 3-option system). This allowed us also to analyze to a certain degree the memory effect.

The doctors added medical information including the tumor's localization and the year of diagnosis (for the cases) as well as any possible diagnosis of hypertension, arthrosis or depression. In order to obtain optimal compliance, the questionnaire was kept very simple.

Statistical method

The main question of this study concerned the risk relation between the diagnosis of cancer and the prior history of FICD, the corresponding age and the treatment of FICD. The data were analyzed using standard methods for case-control studies (15,16) using odds ratios.

Part A: Cancer patients and controls

Odds ratios (ORs) were chosen for description and

tests performed with the usual level of 5%. In order to confine the great amount of data, the confidence intervals are stated for the most important findings only.

The data were further analyzed using an explorative statistical approach. Because in almost 50% of the cases the diagnosis was breast cancer and age might influence the variables of FICD, we analyzed the following subgroups:

- breast cancers vs non-breast cancers
- Age ≤ 60 vs > 60 years

We used two different methods for the analysis of the FICD answers: in version 1 we opposed the two positive to the two negative options; in version 2 we weighted 'yes' as 1, 'uncertain yes' as $\frac{2}{3}$, 'uncertain no' as $\frac{1}{3}$ and 'no' as 0 (which is an arbitrary choice). Furthermore, LW considered a rather strict version 3 using the weights 1 for 'yes' and 'no' and 0 for the other two. This version is not discussed here; however, the results are similar to those achieved with version 2.

Part B: Age of initial cancer diagnosis

We also analyzed the cases separately to explore different relationships. For instance, we considered whether there was a relationship between the age when a cancer was first diagnosed and the patient's FICD history, by means of the Kruskal–Wallis test (17). We limit our presentation to the more important part of the whole statistical analysis.

Results

The mean age was 62.7 years in the case group and 62.5 in the control group, with a range of 27–93 years. There are many more women than men because of the cases of breast cancer (Table 1). The mean number of brothers and sisters, possibly relevant for FICD, is about the same (2.7 in the case group and 2.8 in the control group).

Table 1 gives an overview of the frequency of tumor sites and the age at diagnosis for the 388 cases. We observe different percentages of tumor sites as compared to the overall Swiss population. For instance, we have a high percentage of breast cancer patients due to the large number of female patients. However, the group of non-breast cancer consists of 89 men and 110 women, being more balanced.

Note that the mean age of patients with a breast cancer (53.1 years) is 7 years lower than that of non-breast-cancer patients (60.3 years). Therefore it is reasonable to analyze these different groups individually.

Table 1 Frequency of tumor sites and mean age at initial diagnosis

Localization	Men	Women	Total	Percentage	Mean age
Breast	0	189	189	48.7	53.1
Gastrointestinal	18	28	46	11.9	62.8
Genital	0	42	42	10.8	55.5
Prostate	29	0	29	7.5	71.7
Skin	9	17	26	6.7	54.6
Lungs	7	6	13	3.4	63.5
Ear-Nose-Throat	6	6	12	3.1	60.6
Testicles	7	0	7	1.8	38.0
Others	13	11	24	6.2	60.9
Total	89	299	388	100.0	

Generally, we found that patients with frequent 'classical' FICD also reported to have experienced 'other' FICDs frequently. Older patients tended to report fewer FICDs than younger patients (which could be a memory effect), where the association was stronger for the controls than for the cases.

Part A: Cancer patients and controls

Table 2 shows the ORs for all matched pairs as well as for the subgroups (under age 60, over age 60, breast cancers and non-breast cancers).

The results of this study consistently show a lower cancer risk in patients with a history of FICD, since all significant ORs point in the same direction.

The number of FICDs both 'classical' and 'other' was associated with a decreased cancer risk, especially in the group of non-breast cancer, where for the 'classical' FICD the reduction was 20% per disease ($P = 0.007$) in version 1, 23% ($P = 0.004$) in version 2. The corresponding 95% confidence intervals were [6%; 32%] and [8%; 35%], respectively (Fig. 1).

Considering each 'classical' FICD separately, statistical association with cancer risk was most evident in the group of non-breast cancers, where the strongest cancer risk reduction was found for rubella: the ORs were 0.439 ($P = 0.0006$) in version 1 and 0.377 ($P = 0.003$) in version 2, with corresponding 95% confidence intervals [0.274; 0.702] and [0.221; 0.641], respectively (Fig. 2). A less strong but still significant association was found for chickenpox in two groups, namely the non-breast cancers and those less than 60 years old. In the younger patients we also found a significant risk reduction for measles. A history of pertussis, mumps and scarlet fever did not show a significant effect on the cancer risk.

The age at which the FICD occurred had, in this case-control analysis, no consistent influence on the cancer risk.

Table 2 Odds ratios for the association between a diagnosis of a carcinoma and the anamnestic information

(A) All pairs					(C) Age > 60				
FICD	Version ¹	n ²	OR	P	FICD	Version ¹	n ²	OR	P
Measles	1	375	0.980	.921	Measles	1	230	1.222	.439
	2	375	0.873	.548		2	230	1.253	.425
Mumps	1	372	1.000	1.000	Mumps	1	228	1.122	.557
	2	372	1.009	.957		2	228	1.147	.522
Rubella	1	362	0.742	.055	Rubella	1	221	0.609	.015
	2	362	0.647	.014		2	221	0.535	.007
Pertussis	1	368	0.924	.599	Pertussis	1	224	0.961	.842
	2	368	0.917	.592		2	224	0.992	.971
Scarlet fever	1	366	0.902	.612	Scarlet fever	1	224	1.154	.593
	2	366	0.822	.350		2	224	1.037	.893
Chickenpox	1	372	0.800	.158	Chickenpox	1	227	0.930	.703
	2	372	0.752	.099		2	227	0.893	.594
Number of FICD					Number of FICD				
≥ 1 FICD (vs none)	1	346	0.538	.187	≥ 1 FICD (vs none)	1	209	0.600	.323
Trend 1	1	346	0.912	.108	Trend 1	1	209	0.917	.377
≥ 1 FICD (vs none)	2	346	0.400	.058	≥ 1 FICD (vs none)	2	209	0.417	.100
Trend 1	2	346	0.882	.041	Trend 1	2	209	0.904	.189
Other FICD		314			Other FICD		186		
1-2 times			0.655	.028	1-2 times			0.664	.090
3-4 times			0.573	.046	3-4 times			0.552	.142
More than 4 times			0.440	.001	More than 4 times			0.264	.0004
Reference: never had another FICD					Reference: never had another FICD				
(B) Age ≤ 60					(D) Breast cancers				
FICD	Version ¹	n ²	OR	P	FICD	Version ¹	n ²	OR	P
Measles	1	145	0.708	.277	Measles	1	184	1.037	.893
	2	145	0.446	.043		2	184	0.854	.609
Mumps	1	144	0.850	0.486	Mumps	1	183	1.091	.677
	2	144	0.842	.499		2	183	1.174	.477
Rubella	1	141	1.000	1.000	Rubella	1	177	1.175	.454
	2	141	0.866	.609		2	177	1.040	.872
Pertussis	2	144	0.878	.569	Pertussis	1	181	1.023	.916
	2	144	0.832	.446		2	181	0.959	.852
Scarlet fever	1	142	0.640	.163	Scarlet fever	1	179	0.828	.493
	2	142	0.576	.105		2	179	0.743	.300
Chickenpox	1	145	0.576	.055	Chickenpox	1	180	0.946	.814
	2	145	0.542	.042		2	180	0.939	.802
Number of FICD					Number of FICD				
≥ 1 FICD (vs none)	1	137	0.333	.341	> 1 FICD (vs none)	1	170	0.800	.739
Trend 1	1	137	0.904	.284	Trend 1	1	170	1.054	.532
≥ 1 FICD (vs none)	2	137	0.333	.341	≥ 1 FICD (vs none)	2	170	0.750	.706
Trend 1	2	137	0.844	.101	Trend 1	2	170	1.010	.907
Other FICD		128			Other FICD		158		
1-2 times			0.668	.208	1-2 times			0.692	.166
3-4 times			0.631	.251	3-4 times			0.756	.473
More than 4 times			0.687	.301	More than 4 times			0.829	.598
Reference: never had another FICD					Reference: never had another FICD				

Table 2 (cont'd)

FICD	Version ¹	n ²	OR	P
(E) Non-breast cancers				
Measles	1	191	0.917	.768
	2	191	0.895	.740
Mumps	1	189	0.911	.666
	2	189	0.852	.501
Rubella	1	185	0.439	.0006
	2	185	0.377	.0003
Pertussis	1	187	0.833	.394
	2	187	0.875	.565
Scarlet fever	1	187	1.000	1.000
	2	187	0.925	.798
Chickenpox	1	192	0.698	.093
	2	192	0.617	.044
Number of FICD				
≥ 1 FICD (vs none)	1	176	0.375	.147
Trend 1	1	176	0.801	.007
≥ 1 FICD (vs none)	2	176	0.273	.046
Trend 1	2	176	0.771	.004
Other FICD		156		
1-2 times			0.601	.071
3-4 times			0.398	.026
More than 4 times			0.240	.0001
Reference: never had another FICD				

¹Weights: Version 1: 1 = yes or uncertain yes
 0 = no or uncertain no
 Version 2: 1 = yes, 2/3 = uncertain yes,
 1/3 = uncertain no, 0 = no

²Number of pairs

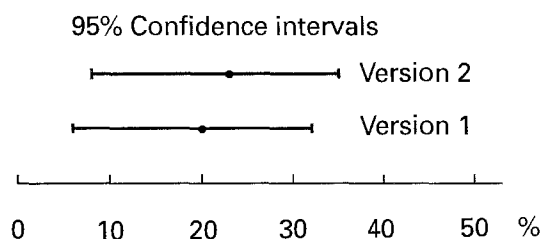


Fig. 1 Confidence intervals for the decrease of OR per FICD.

Also, the non-classical FICDs reveal a significant association with the cancer risk, in particular in the group of non-breast cancers.

The study also showed significant relationships between the treatment of FICD and the cancer risk. We noted that a history of external applications (frictions and compresses) was associated with a lower cancer risk in the group of non-breast cancers (OR = 0.159, *P* = 0.002, 95% CI = [0.051; 0.498]) as well as in the group of those over the age 60 (OR = 0.282, *P* = 0.003, 95% CI = [0.123; 0.644]).

Part B: Age at initial cancer diagnosis

Although having a FICD history seems to lower the cancer risk (part A), those cancer patients who did have such a history had their cancer diagnosis significantly earlier in life than those who did not. The age cancer was first diagnosed was decreased by 1.3 years per childhood disease (*P* = 0.021, 95% CI = [0.2; 2.4]). The strongest age reductions were found for chickenpox (5-6 years, *P* = 0.0001, 95% CI = [2.9; 8.4]), for rubella (4-5 years, *P* = 0.001, 95% CI = [1.3; 8.1]), for pertussis (2-3 years, *P* = 0.044, 95% CI = [0.1; 5.4]) and for measles within the group of the over-60-year-olds (4-5 years, *P* = 0.012, 95% CI = [1.0; 8.4]). No association was found for mumps or scarlet fever.

Discussion

Great attention was paid to the reduction of observer bias because of the comments by Abel et al (14). Therefore the questionnaire was filled out by the patients without help of the physicians, who had to complete the questionnaire only after collection with same anamnestic information.

The possibility of anamnestic bias could not be eliminated completely. It is possible that carcinoma patients differ systematically from controls in regard to their ability and willingness to give reliable anamnestic information on their childhood diseases.

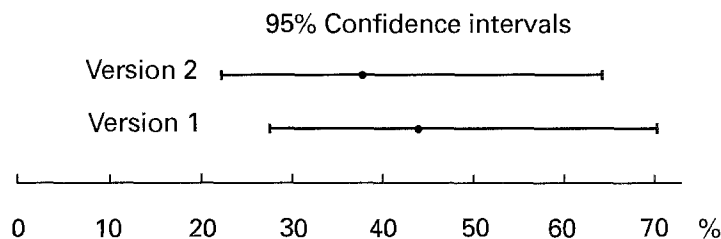


Fig. 2 Confidence intervals for the OR for rubella in the group of non-breast cancers.

This problem was extensively discussed by Abel et al (14), who came to the conclusion that an anamnestic bias in their own study was unlikely. We could not observe in our study that this bias influenced our results strongly, because the different versions of weighting the given answers were revealing similar conclusions. We did not ask the patients to report on the severity of their FICDs. This would be even more dependent on the memory of the patients. But we cannot exclude the possibility that this factor may have influenced our results. Another factor might be the use of antibiotics, which was asked for in our questionnaire. For obvious reasons, there are few cases in our study where antibiotics were used in the treatment of FICD. We do not believe that these few cases had an influence on our results.

The present study reveals fairly consistently a lower cancer risk for patients with a history of FICD. Our data confirm our basic hypothesis and are also consistent with those from previous case-control studies. However, the associations are not as evident as expected. While there are significant associations within the group of non-breast cancers, no significant relationships were found within the group of breast cancers. In regard to the tumor site, all previous investigations differ widely from each other. Abel (14) states without further specification: 'There were distinct differences between the cancer sites in odds ratios for various childhood infections'. This suggests that, in subsequent studies, the different cancer sites should be analyzed in more details. This is not possible with our study because of the small sample sizes of the subgroups.

The finding that a FICD history is associated with an earlier cancer diagnosis is contrary to our hypothesis and needs further investigations for its biological interpretation. The population of our cases, selected in offices of anthroposophic general practitioners, is representative for the general population of Switzerland and allows us no generalization of our results.

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Exhibit N

contribute aptitudes which they do not possess, hence there is exchange.

Christ lived and He showed us how to turn our longings to success: we must think of others not of ourselves. It has never been refuted that He rose from the dead, and His spirit is with us if we want to accept it.—I am, etc.,

MARY D. SMITH

Glasgow

Infantile Hodgkin's Disease: Remission after Measles

SIR,—The remission of Hodgkin's disease in children after measles is a rare event.^{1,2} I should like to report a cure seen at the Paediatric Clinic (Professor S. Bessa), University Hospital, Coimbra.

A 23-month-old caucasian male was seen for the first time in April 1970 with a large mass in the neck due to hypertrophy of the left cervical lymph nodes (see fig.). The mass had first been noticed in November 1969. The child had no fever or pruritus, the chest x-ray film was normal, the E.S.R. was 9 mm in the first hour, and the haemogram was normal with no eosinophilia. An intradermal skin test to *Candida albicans* antigen 1 : 100 (Bencard) was negative. A diagnosis of predominantly lymphocytic Hodgkin's disease was made on the histopathological findings of lymph node biopsy (Professor R. Trincao).

Before radiotherapy could be started the child developed measles. Much to our surprise the large cervical mass vanished without further therapy. The chest x-ray picture remained normal but the haemogram showed pronounced leucopenia (3,400/mm³). It was decided not to start radiotherapy, and the child remained symptom free for six months. New intradermal tests for *Candida* were done 2-5 months after the measles episode, and this time they were positive. The immunoglobulins remained normal.

In November 1970 the child's mother noticed he had erythematostash soon after he had drunk some wine. It covered the face and the area of the neck corresponding to the site of the lymph node biopsy, where enlarged lymph nodes were again palpable (fig.). The haemogram, chest x-ray film ex-

amination, and *Candida* skin test were repeated. There was pronounced eosinophilia (11%), the chest x-ray film remained normal, and the response to *Candida* was again negative. Another biopsy showed Hodgkin's disease of mixed cellularity. In view of this relapse irradiation with cobalt-60 was started, and after a total dose of 3,000 rad at the rate of 300 rad every other day (Portuguese Institute of Oology, Coimbra) the child re-entered a remission period which has lasted for 18 months.—I am, etc.,

H. CARMONA MOTA

Department of Paediatrics, University of Coimbra, Portugal

¹ Hernandez, S. A., *Archives Cubanos de Cancerologia*, 1949, 8, 26.
² Zygiert, Z., *Lancet*, 1971, 1, 593.

Research Investigations in Adults

SIR,—With reference to the tape-recorded discussion on this subject (28 April, p. 220) there must be few who would dispute the necessity and value of ethical committees in all hospitals, especially where there is a research interest, but their work must extend further than the walls of a committee room where the members deliberate on the moral and scientific aspects of any project.

As a ward sister in the clinical research centre at Northwick Park I was very aware of conflict experienced by those concerned with the day-to-day care of patients involved in research. The question of informed consent is indeed difficult. I always felt it my responsibility to be sure that any patient understood fully what was happening to him, whether or not it was research, and that he knew he had the right to refuse without any repercussions. Even though most consultants are good at explanations, there are still many patients who are afraid of them and feel happier asking questions of a nurse or junior doctor whom they see every day. In fact this pays dividends, as once the patient feels involved in his own investigation or treatment he is more co-operative and everything runs more smoothly. On several occasions I was asked, "Is this the guinea-pig hospital?" and it is only by being absolutely honest with patients and their re-

latives that the community's trust in its hospital will be maintained, especially when routine procedures become more complex and less comprehensible.

This draws to light the dual position in which the nurse (and also to a large extent the junior hospital doctor) in a research team finds herself. On the one hand she feels it her duty to protect the patient against the enthusiasms of investigators, and on the other she is part of a team striving to achieve a particular goal, and this can sometimes present difficulties. If she is too much on the side of the patient she may be pressurized by the medical staff and if she is inclined the other way she (quite rightly) has to justify the investigations to the junior nurses.

A third difficulty, and possibly the most disturbing, is that it can be very difficult to distinguish between clinical research and beneficial investigation. I trained as a nurse, not a scientist; my knowledge of the sciences and technology is basic, and therefore explanations and understanding of some projects can be difficult. (Indeed, can all doctors understand one another's work?) In this situation an investigator could "pull the wool over the eyes" of the ward sister or she might, wrongly, think this is happening. If her trust and co-operation are to be maintained it is vital that there is someone to whom she can turn for unbiased advice.

Lastly, never let it be said that any procedure is trivial; even a 24-hour timed urine collection may cause anxiety if it means that a mother has to spend an extra night away from her young children, and I have known the fear of venepuncture the next morning disturb a patient's sleep.

As Dr. M. D. Eilenberg pointed out in the discussion, the best way to ensure ethical control is to establish an "ethical climate." This will not be achieved if the committee is a remote body sitting in an ivory tower. It must make itself aware of the effect of its decisions and be accessible to the opinions of everyone—including the most junior of students and the patients themselves—if there is to be the mutual trust vital for the survival of any institution.—I am, etc.,

JANET E. ANDREWS

Iford, Essex

Treatment of S.L.E Nephritis

SIR,—The article on treatment of systemic erythematosis (S.L.E.) nephritis with chlorambucil by Dr. M. L. Snaith and others (28 April, p. 197) provokes comment. In the first place it seems that when faced with steroid intolerance, rather than try alternate-day therapy, high-protein diet, combination with diuretics, and other immunosuppressives such as azathioprine to achieve steroid-sparing effect, they have chosen to change to chlorambucil. This is a nitrogen mustard derivative like cyclophosphamide, which they have shown to produce amenorrhoea, and it is surprising that they claim that it produces less marrow suppression. Such has not been my experience in treating cases of cold agglutinin haemolytic anaemia with this drug.

I find the suggestion that chlorambucil could be superior to cyclophosphamide equally surprising; no theoretical basis for this is given. While not denying that cyclophosphamide therapy has its complications,

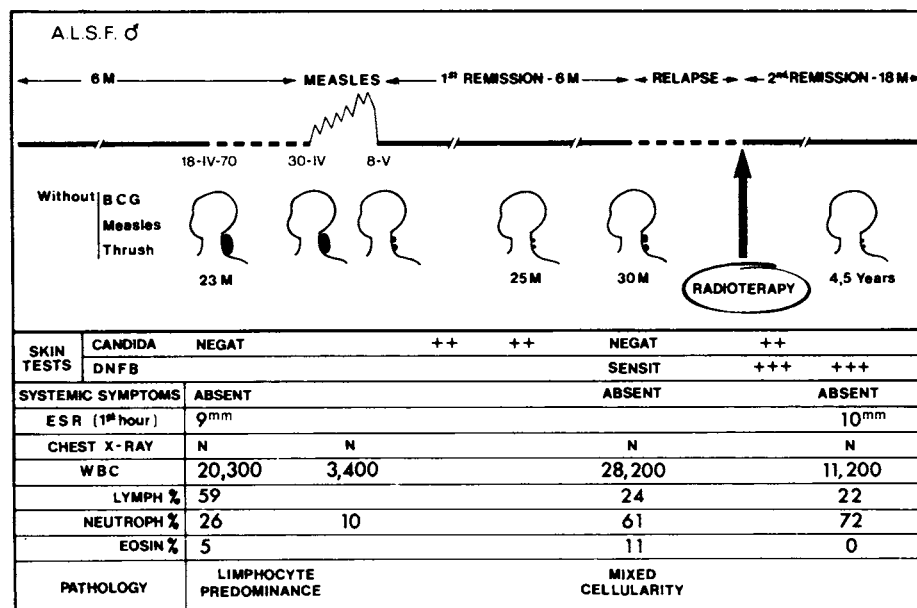


Exhibit O



Cancer Stat Facts: Non-Hodgkin Lymphoma

(<https://seer.cancer.gov>)

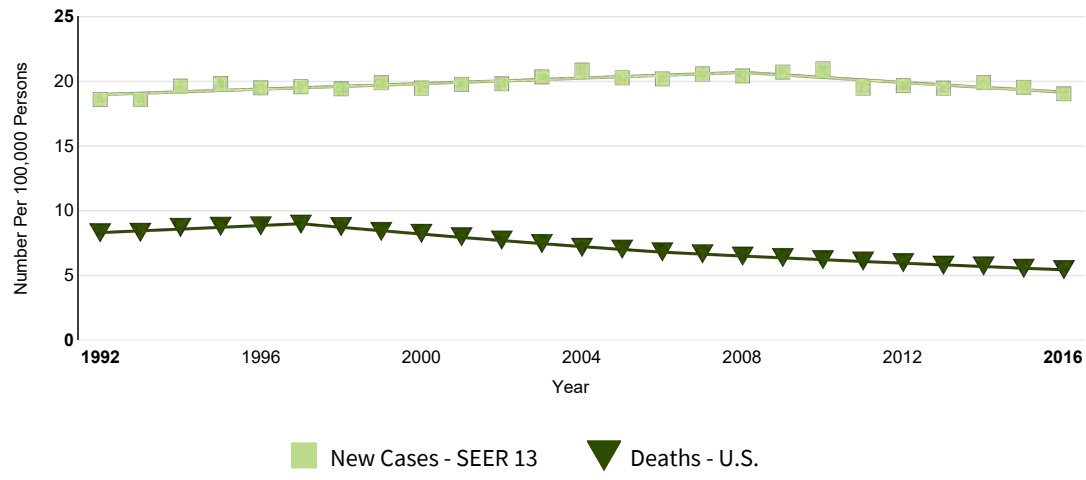
Statistics at a Glance

At a Glance

Estimated New Cases in 2019	74,200
% of All New Cancer Cases	4.2%

Percent Surviving 5 Years
72.0%
2009-2015

Estimated Deaths in 2019	19,970
% of All Cancer Deaths	3.3%



Modeled trend lines were calculated from the underlying rates using the Joinpoint Trend Analysis Software.

[View Data Table](#)

Number of New Cases and Deaths per 100,000: The number of new cases of non-Hodgkin lymphoma was 19.6 per 100,000 men and women per year. The number of deaths was 5.6 per 100,000 men and women per year. These rates are age-adjusted and based on 2012-2016 cases and deaths.

Lifetime Risk of Developing Cancer: Approximately 2.2 percent of men and women will be diagnosed with non-Hodgkin lymphoma at some point during their lifetime, based on 2014-2016 data.

Prevalence of This Cancer: In 2016, there were an estimated 694,704 people living with non-Hodgkin lymphoma in the United States.

- Survival Statistics
- Number of New Cases and Deaths
- Trends in Rates
- More About This Cancer

These stat facts focus on population statistics that are based on the U.S. population. Because these statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient. To see tailored statistics, browse the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). To see statistics for a specific state, go to the State Cancer Profiles (<https://seer.cancer.gov><https://statecancerprofiles.cancer.gov/>).

The statistics presented in these stat facts are based on the most recent data available, most of which can be found in the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). In some cases, different year spans may be used. Estimates for the current year are based on past data.

Cancer is a complex topic. There is a wide range of information available. These stat facts do not address causes, symptoms, diagnosis, treatment, follow-up care, or decision making, although links are provided to information in many of these areas.

Exhibit P



Cancer Stat Facts: Hodgkin Lymphoma

(<https://seer.cancer.gov>)

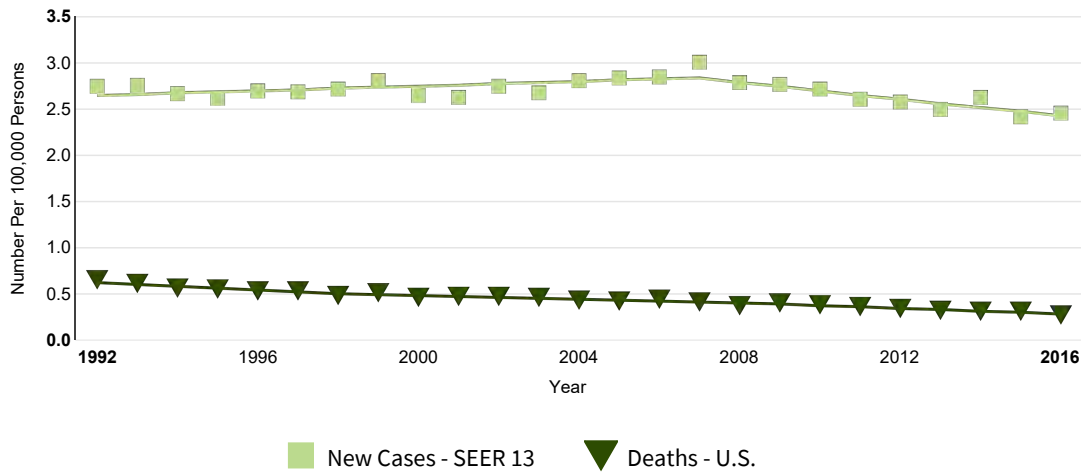
Statistics at a Glance

At a Glance

Estimated New Cases in 2019	8,110
% of All New Cancer Cases	0.5%

Percent Surviving 5 Years
86.6%
2009-2015

Estimated Deaths in 2019	1,000
% of All Cancer Deaths	0.2%



Modeled trend lines were calculated from the underlying rates using the Joinpoint Trend Analysis Software.

[View Data Table](#)

Number of New Cases and Deaths per 100,000: The number of new cases of Hodgkin lymphoma was 2.7 per 100,000 men and women per year. The number of deaths was 0.3 per 100,000 men and women per year. These rates are age-adjusted and based on 2012-2016 cases and deaths.

Lifetime Risk of Developing Cancer: Approximately 0.2 percent of men and women will be diagnosed with Hodgkin lymphoma at some point during their lifetime, based on 2014-2016 data.

Prevalence of This Cancer: In 2016, there were an estimated 210,974 people living with Hodgkin lymphoma in the United States.

- Survival Statistics
- Number of New Cases and Deaths
- Trends in Rates
- More About This Cancer

These stat facts focus on population statistics that are based on the U.S. population. Because these statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient. To see tailored statistics, browse the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). To see statistics for a specific state, go to the State Cancer Profiles (<https://seer.cancer.gov><https://statecancerprofiles.cancer.gov/>).

The statistics presented in these stat facts are based on the most recent data available, most of which can be found in the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). In some cases, different year spans may be used. Estimates for the current year are based on past data.

Cancer is a complex topic. There is a wide range of information available. These stat facts do not address causes, symptoms, diagnosis, treatment, follow-up care, or decision making, although links are provided to information in many of these areas.

Exhibit Q



Cancer Detection and Prevention 30 (2006) 83–93

**Cancer
Detection
and
Prevention**

www.elsevier.com/locate/cdp

Review

Acute infections as a means of cancer prevention: Opposing effects to chronic infections?

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Accepted 9 November 2005

Abstract

Purpose: Epidemiological studies have found an inverse association between acute infections and cancer development. In this paper, we review the evidence examining this potentially antagonistic relationship. **Methods:** In addition to a review of the historical literature, we examined the recent epidemiological evidence on the relationship between acute infections and subsequent cancer development in adult life. We also discuss the impact of chronic infections on tumor development and the influence of the immune system in this process. **Results:** Exposures to febrile infectious childhood diseases were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined, significant in the latter two groups. Epidemiological studies on common acute infections in adults and subsequent cancer development found these infections to be associated with reduced risks for meningioma, glioma, melanoma and multiple cancers combined, significantly for the latter three groups. Overall, risk reduction increased with the frequency of infections, with febrile infections affording the greatest protection. In contrast to acute infections, chronic infections can be viewed as resulting from a failed immune response and an increasing number have been associated with an elevated cancer risk. **Conclusion:** Infections may play a paradoxical role in cancer development with chronic infections often being tumorigenic and acute infections being antagonistic to cancer.

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Keywords: Fever; Cancer prevention; Infection; Leukocytes; Spontaneous regression

1. Introduction

A key vision of the World Health Organization has been to create “a world in which all people at risk are protected against vaccine-preventable diseases” [1]. An admirable goal in light of the considerable morbidity and mortality infectious diseases continue to inflict throughout the world. Yet, at the same time one cannot help but wonder whether the infectious diseases that have plagued humanity for millennia could somehow incur more intangible benefits. For example, the old adage “what does not kill me makes me stronger” may in some sense be applied to the influence of acute infectious disease on cancer development. In a 1929 review on the topic, Pearl commented “that there is an

antagonism between cancer and infectious diseases . . . is a medical judgment which has existed from remote times” [2]. In this paper, we review past and present evidence for an antagonistic relationship between acute infectious disease and cancer, and its relevance to cancer prevention. We also explore the paradoxical role chronic infections may play in cancer development.

Acute infections may be defined as those that generally have a rapid onset and last for a relatively short period of time [3]. These infections are often associated with an “acute phase reaction”—an early local inflammatory reaction, consisting of fever (a cytokine-mediated rise in core temperature), an increased synthesis in the liver of acute phase reactants, as well as a host of other immunologic, endocrinologic, neurologic and physiologic changes [4]. Chronic infections may be defined as afebrile infections lasting many years, which may have limited or no disease symptoms [3].

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Moreover, chronic infections may be regarded as a consequence of a failed or misguided immune response. Infections do not always fit into these two distinct categories. For example, a chronic infection at its outset may trigger an acute phase reaction, it may have recurrent acute phases, and may develop progressively more severe symptoms over time. Additionally, a pathogen that causes an acute infection in one individual may cause a chronic infection in another. For simplicity, we refer to infections as being either acute or chronic; however, in terms of their influence on cancer, we argue that the development of the acute phase reaction is an important determinate in cancer prevention.

2. Materials and methods

We have previously reviewed reports of spontaneous cancer regression and its frequent association with acute infections, and febrile infections in particular [5–7]. This led us to the hypothesis that if acute infections could induce cancer regression, then frequent acute infections within a population may also be able to reduce cancer incidence. Thus, the aim of the present study was to examine the epidemiologic evidence (case–control and cohort studies) investigating the association between acute infections and subsequent cancer development in adults. Papers that reported original research were identified by an electronic database search in PubMed (up to 2005) and EMBASE (1980–2005). Relevant papers were identified using the following keywords: neoplasms, infection, fever, epidemiologic studies, case–control studies, and cohort studies. Furthermore, we hand searched the bibliographies of these epidemiological studies and related review articles for additional publications on the subject. The odds ratios (OR) or relative risks (RR) and associated p -values or 95% confidence intervals (95% CI) from papers published since 1960 were summarized in structured tables to allow for comparison and discussion of findings.

As a background to these recent studies, we examined the historical literature on the association between infections and cancer development, as well as, reports of spontaneous tumor regression occurring in cancer patients with concomitant infections. The historical literature reviewed included textbooks on cancer written previous to 1950, historical articles found in the bibliographies of papers relevant to the topic reviewed, and from a search of *Index Medicus* during the period 1879–1926. Finally to contrast the data on acute infections, we review of the influence of chronic infections on cancer development.

3. Historical perspectives on infection and cancer

3.1. Acute infections and spontaneous cancer regression

Some of the evidence supporting the concept that acute infectious disease may be antagonistic to cancer relates to

the repeated observations of spontaneous cancer regression in patients with coincident infections [5]. An early example is the report by Dupuytren [8] in 1829 of a woman with an extensive carcinoma of the breast who had refused surgery. Eighteen months later she was bedridden, cachectic and almost moribund. At this time, the patient became feverish with vomiting. Her now extensive tumor became inflamed and gangrenous. Three incisions were made into the tumor to evacuate a large quantity of viscous fluid. Within eight days the tumor had regressed by one-third. By the 4th week, the disease was no longer evident. Interestingly, the great frequency of such observations led to the development of active immunotherapy treatments for cancer in the 18th and 19th centuries [5]. Sometimes septic dressings would be applied to ulcerated tumors or the surgical incision would be left open to facilitate infection or often suppurating sores would be intentionally established [6].

The most conclusive evidence, however, that acute infections may counter tumor growth comes from the work of William Coley, whose career spanned from 1891 to 1936. At the turn of the century Coley, a surgeon, developed a killed bacterial vaccine for cancer consisting of the gram positive *Streptococcus pyogenes* and gram negative *Serratia marcescens*. His initially encouraging results in inducing tumor regression with repeated inoculations [9] was followed by similar successes reported by contemporaries who experimented with his vaccine [10–12]. It is documented that Coley's method of treatment could induce the complete regression of extensive metastatic disease [12]. Although there was considerable variation from one individual to the next, after many hundreds of cases, Coley confirmed his impressions that mimicking a *repetitive* acute febrile response was the key factor necessary to provoke and maintain tumor regression [6]. His treatment gradually fell out of favor following his death in 1936. By that time, radiation and increasingly chemotherapy had become mainstays of treatment for cancer and required less time, effort, and individualization than Coley's vaccine.

3.2. Acute infections in cancer prevention

If overt cancer can regress in association with acute infections, why not occult cancers and precancerous lesions? In fact, the impression that infections may *prevent* cancer arose from the often repeated observation that individuals who developed cancer generally had unexceptional medical histories. For example, Didot commented in 1852 that if one studies the prior health of cancer patients, one notes since the time of Hippocrates their previous health has been good until the onset of cancer [13]. In 1854, the physician Laurence stated, “as a rule, it will be found that cancerous patients have otherwise been remarkably free of disease” [14]. A similar perspective was later provided by the French physician, Lambotte, in 1896 [15]. He suggested that antecedent erysipelas (i.e. *S. pyogenes*) and other suppurative diseases rarely occurred in the cancer patient and that

“these maladies, by their vaccinal action protect against cancer.”

Other authors in the 19th and early 20th century noted a peculiar absence of cancer in individuals prone to a variety of acute and chronic infectious diseases. Both Soegaard [16] and Kobayashi [17] commented that cancer was extremely rare in patients with leprosy. Voussoughi [18] observed that cancer and amebic dysentery were frequently seen in Iran, but never in the same individual. Similar inverse correlations were found for cancer and gonorrhoea [19], syphilis [20,21], malaria [21–24], and tuberculosis [25,26], where in the latter, Haldane [27] stated that perhaps the majority of pathologists “maintain that the two diseases are exclusive.” Nevertheless, these studies were based upon case series and empirical observations that could have been confounded by the early age of mortality in those with infectious disease.

The statistical rigor of such studies however was gradually improving over time. In 1912, Levin undertook a comparative survey of cancer incidence in American Indians and the white population in the same localities [28]. He remarked that in the same geographical region, the proportion of American Indians over 50 years of age was higher than in their white neighbors, yet cancer was extremely rare in the American Indians. Smith et al. [29,30] used standardized mortality ratios to compare the rates of infectious diseases and cancer among white and Indian populations in Canada and the United States. Cancer mortality rates were significantly lower in the Indians, yet rates for infectious and parasitic diseases were six times higher. Although some of the infections considered antagonistic to cancer were generally chronic in nature, how the immune system responds to such infections may have been a key element. For example, in an autopsy study by Pearl [2], the prevalence of active versus healed tuberculosis was compared in subjects with cancer and without cancer. He drew from an autopsy series of 6670 post mortem examinations, which included 816 cases of malignant disease. These subjects were then matched by age, sex, race and approximate time of death to 816 noncancerous controls. Cancer prevalence was significantly lower in subjects with evidence of active versus healed tuberculosis [OR = 0.36, 95% CI 0.26–0.50]. Thus, the degree of immune activation within each individual may be a key factor with respect to cancer antagonism.

During this past century, the magnitude of the immune response that develops following many acute infections has changed considerably [6]. In the pre-antibiotic era, when a patient developed a bacterial or other parasitic infection, it would generally run its course with little effective intervention. However, the widespread introduction of antibiotics following World War II led to rapid intervention of such illnesses, reducing both disease intensity and duration. At the same time, the routine use of antipyretics to treat febrile patients (which suppresses the acute phase response) became increasingly popular. Thus, as the clinical course of these infections has changed, their influence on

malignant disease may have also changed over the past century [6].

4. Epidemiology of infection and cancer

4.1. Changing patterns in the 20th century

Only in the last century has there been a more quantitative evaluation of the relationship between infections and cancer. In 1916, Hoffman [31] examined changing mortality rates from various diseases in New York, Boston, Philadelphia, and New Orleans, comparing two consecutive eras: 1864–1888 and 1889–1913. Significant declines were observed for major infectious causes of death including: pulmonary tuberculosis, stomach and intestinal diseases, diphtheria and croup, scarlet fever, typhoid and typhus fever, smallpox, yellow fever and Asiatic cholera. Yet during that same time period, the cancer death rate increased by over 55%. In fact, an editorial on this phenomenon made the ironic conclusion that “it would appear possible that public health and sanitation, as developed throughout the years, may prove to have been a two-edged sword” [32]. Was this increase in cancer simply due to an increase in life expectancy? Jacobsen in 1934 [33] similarly contended that the rising incidence of cancer in the early 20th century resulted from the progressive decrease in acute infectious diseases. He discussed modern public health and sanitary measures that led to a decline in the incidence of many infectious diseases. Yet, he cited evidence on the greater occurrence of cancer in all age groups to support his contention that it was not simply due to the general increase in life expectancy. A number of studies during the first half of the 20th century supported this argument, noting a history of significantly fewer acute infections in cancer patients compared to those without the disease [34–39]. The contention that acute infections could be antagonistic to cancer development was also tested in a more recent study comparing infectious disease mortality and cancer mortality rates from 1895 to 1963 in Italy [40]. In comparing age-specific mortality rates, an inverse correlation between infectious disease and cancer mortality was observed. Moreover, every 2% reduction in infectious disease mortality was followed by a 2% increase in cancer mortality with a 10 year interval.

4.2. Socioeconomic status, infection and cancer incidence

In 1916, a study in Edinburgh examined cancer and tuberculosis mortality by class of residence occupied by the deceased [31]. Socioeconomic status was inversely associated with tuberculosis mortality, whereas, it was positively associated with cancer mortality. The author concluded that “available evidence is rather to the effect that cancer is chiefly a disease of the well-to-do.” Although the competing mortality risks for tuberculosis and cancer could explain

those findings, recent age-adjusted studies in developed countries continue to show a higher incidence of many cancers among the affluent, including: colon, kidney, breast, testes, prostate, melanoma and other skin cancers [41–43]. In contrast, the frequency of many infections in adults and children, such as abdominal, respiratory tract and other acute infections, is inversely correlated with socioeconomic status [44–50]. This relatively higher incidence of acute infections may in turn be a factor in the reduced incidence of some cancers in lower socioeconomic groups. On the other hand, some cancers are more prevalent in the lower social classes, notably lung, liver, cervical and stomach cancer [41–43]. The higher incidence of lung and some liver cancers can be explained by higher tobacco and alcohol use [42,43]; whereas cervical and stomach as well as liver cancers are associated with chronic, rather than acute, infections (human papilloma virus (HPV), *Helicobacter pylori*, and Hepatitis B and C, respectively) that are also more prevalent amongst the lower social classes [51–54].

4.3. Epidemiological studies of acute infections and cancer

Recent epidemiological studies have consistently found an inverse association between acute infectious diseases and

cancer risk. Table 1 summarizes studies examining the association between febrile infectious childhood diseases (FICD) and subsequent cancer risk. Overall, exposures to common FICD were associated with a reduced risk for melanoma [58], ovarian cancer [55,56], and multiple cancers combined [57,59], although only significant in the latter studies [55–57,59]. An exception was a recent study by Hoffman et al. [60]. Chickenpox and mumps were associated with an increased risk of cancer, only significant for mumps [OR = 2.61, 95% CI 1.18–5.80]; whereas, a nonsignificant reduced risk was seen for measles and rubella [60]. In the study by Kolmel et al. [58], FICD were found to be associated with a lesser degree of protection against melanoma than adult febrile infections. Albonico et al. [59] specifically compared the effects of FICD on tumors diagnosed before and after age 60. Reductions in cancer risk were generally much stronger for tumors diagnosed before age 60. These studies suggest that childhood diseases may afford some protection against cancer, which decreases with advancing age. Alternatively, FICD may be a marker for individuals who are generally more prone to infections (e.g. related to socioeconomic status) and that infections occurring in the latter years provide greater protection against cancer.

Other epidemiological studies have looked at the association between common acute infections in adults

Table 1

Epidemiological studies examining the association between febrile infectious childhood diseases (FICD) and the subsequent development of cancer

Cancer	Case/control	Infection type	Outcome (95% CI) ^a highest vs. lowest	Year [reference]
Ovary	97/97 ^b	Measles Mumps Rubella	No association Reduced risk ($p = 0.007$) No association	1966 [55]
Ovary	300/300 ^b	Chickenpox Measles Mumps Rubella	OR = 0.70 (0.51–0.97) OR = 0.50 (0.32–0.76) OR = 0.65 (0.23–0.90) OR = 0.65 (0.47–0.92)	1977 [56]
Multiple cancers	255/255 ^b	Chickenpox Measles Mumps Rubella	OR = 0.66 (0.45–0.97) OR = 0.61 (0.34–1.09) OR = 0.83 (0.55–1.26) OR = 0.72 (0.45–1.16)	1991 [57]
Melanoma	139/271 ^c	Chickenpox Measles Mumps Rubella	OR = 0.88 (0.52–1.92) OR = 0.73 (0.35–1.54) OR = 0.86 (0.53–1.40) OR = 0.69 (0.39–1.23)	1992 [58]
Non-breast cancers	379/379 ^b	FICD: ≥ 1 Chickenpox Measles Mumps Rubella	OR = 0.27 ($p = 0.046$) OR = 0.62 ($p = 0.044$) OR = 0.90 ($p = 0.740$) OR = 0.85 ($p = 0.501$) OR = 0.38 ($p = 0.003$)	1998 [59]
Multiple cancers	111/109 ^c	Chickenpox Measles Mumps Rubella	OR = 2.09 (0.92–4.78) OR = 0.76 (0.22–2.56) OR = 2.61 (1.18–5.80) OR = 0.91 (0.38–2.16)	2002 [60]

OR: odds ratio, CI: confidence interval, FICD: febrile infectious childhood diseases.

^a Results in bold are statistically significant.

^b Age matched or no significant difference in age between groups.

^c Adjusted for age and other risk factors.

Table 2
Epidemiological studies examining the association between acute infections and cancer

Cancer	Cases/controls	Infection type	Outcome (95% CI) ^a highest vs. lowest	Year [reference]
Melanoma and other cancers	110/126 ^b	Frequent colds: smokers	OR = 0.39 (0.15–1.02)	1983 [61]
		Frequent colds: Non-smokers	OR = 0.07 (0.05–0.15)	
		Frequent colds: Combined	OR = 0.20 (0.12–0.35)	
Multiple cancers	108/206 ^c	Colds: ≥1 per year	OR = 0.71 (0.45–1.25)	1986 [62]
Multiple cancers	204/1310	Fever: >39 °C for more than 3 days		1987 [63]
		Rarely (>5 in a lifetime)	RR = 0.37 (0.19–0.47)	
		Several times (5–30 times)	RR = 0.25 (0.13–0.30)	
		Frequently (several times per year)	RR = 0.29 (0.13–0.37)	
Multiple cancers	255/255 ^b	Colds/flu: 1–2 per year	OR = 0.61 (0.38–0.97)	1991 [57]
		Colds/flu: ≥3 per year	OR = 0.18 (0.05–0.69)	
		Abdominal flu	OR = 0.95 (0.60–1.50)	
		Febrile abdominal flu	OR = 0.43 (0.18–1.00)	
Colorectal		Abdominal flu	OR = 0.48 (0.24–0.97)	
		Febrile abdominal flu	OR = 0.15 (0.03–0.68)	
Glioma Meningioma	1178/1987 ^b	Acute febrile infections: ≥1–2 per year	OR = 0.72 (0.61–0.85)	1999 [64]
	331/1123 ^b	Acute febrile infections: ≥1–2 per year	OR = 0.73 (0.54–1.00)	
Melanoma	603/627 ^c	Severe febrile infections in past 5 years		1999 [65]
		1	OR = 0.75 (0.56–1.01)	
		2–3	OR = 0.68 (0.44–1.04)	
		≥4	OR = 0.18 (0.02–0.91)	
		General febrile infections in past 5 years		
		1	OR = 0.98 (0.66–1.45)	
		2	OR = 0.89 (0.61–1.28)	
3	OR = 0.58 (0.38–0.89)			
≥4	OR = 0.53 (0.35–0.79)			
Multiple cancers	111/109 ^c	Colds: ≥1 per year	OR = 0.69 (0.51–0.92)	2002 [60]
		Fever: >39 °C in past 5 years	OR = 0.90 (0.10–8.60)	

OR: odds ratio, CI: confidence interval, RR: relative risk.

^a Results in bold are statistically significant.

^b Age matched or no significant difference in age between groups.

^c Adjusted for age and other risk factors.

and cancer development (Table 2). These studies found that acute infections were associated with a reduced risk for glioma [64], meningioma [64], melanoma [61,65] and multiple cancers combined [57,60,62,63], although of borderline significance for meningioma [OR = 0.73, 95% CI 0.54–1.00] [64] and not significant for one study of multiple cancers [OR = 0.71, 95% CI 0.45–1.25] [62]. Overall, risk reduction increased with the frequency of infections [57,63–65], and febrile infections in particular, were found to afford the greatest protection against cancer development [57,63–65]. Interestingly, in the study by Abel et al. [57] although abdominal infections were associated with a trend towards a reduction in overall cancer risk [abdominal flu OR = 0.95, 95% CI 0.60–1.50; febrile abdominal flu OR = 0.43, 95% CI 0.18–1.00], the reduction in risk was greatest and significant for colorectal cancers [abdominal flu OR = 0.48, 95% CI 0.24–0.97; febrile abdominal flu OR = 0.15, 95% CI 0.03–0.68]. Thus, protection against tumor development may be particularly enhanced within regions of previous infection. This is also

observed in cases of infection-associated spontaneous tumor regression, where regression is most often observed when the nidus of infection is within the vicinity of the tumor [6,7,66].

Although the results in Tables 1 and 2 were generally consistent, deficiencies in some of the studies reviewed were noted. For example, several studies included a large number of multiple comparisons without employing statistical procedures to adjust for the multiplicity [55,57,59]. In the study of ovarian cancer by West [55], controls were women with benign ovarian tumors—both conditions may have had a similar etiology. Other biases that could have influenced the findings in these studies could include accurate estimation of infectious history and recall bias between cases and controls. The only prospective study among those reviewed was conducted by Grossarth-Maticek et al. [63] on subjects 40–79 years of age at entry. Beginning in 1966, investigators followed this cohort for 10 years, and reported a complete follow-up on all 1310 subjects by 1976. Cancer incidence was determined through examination of medical

Table 3
Examples of some chronic infections associated with cancer development

Infection	Cancer site or cancer	Reference
Viruses		
Epstein–Barr virus	Lymphomas, nasopharyngeal cancer	[67]
Hepatitis B, C virus	Liver cancer, non-Hodgkin's lymphoma	[68,69]
Human herpesvirus type 8	Kaposi sarcoma	[70]
Human immunodeficiency virus	Kaposi sarcoma, non-Hodgkin's lymphoma	[71]
Human papillomavirus	Cervix, anogenital cancer	[72]
Human T-cell lymphotropic virus	Leukemias, lymphomas	[73]
Bacteria		
<i>Helicobacter pylori</i> , <i>H. Heilmannii</i>	Gastric cancer, MALT lymphomas	[74,75]
<i>Salmonella</i>	Hepatobiliary cancer	[76]
Parasites		
<i>Schistosoma haematonium</i>	Bladder cancer	[77]
<i>Schistosoma japonicum</i>	Liver, colorectal cancer	[78]
Liver flukes: <i>Opisthorchis viverrini</i> , <i>Clonorchis sinensis</i>	Cholangiocarcinoma	[79]

MALT: mucosa-associated lymphoid tissue.

records and/or death certificates. However, the relative risks were based upon crude cancer incidence rates, without adjustment for age [63]. Thus, more rigorous epidemiological research, particularly prospective cohort studies, is required to provide further insight into this relationship.

5. Chronic infections and cancer

Ironically, in contrast to acute infections, many chronic infections are known to lead to malignant changes over time. An increasing number of chronic viral, bacterial and parasitic infections in humans have been implicated in the development of a variety of tumor types (Table 3). The means through which these infections induce malignant change are many [80–82]. Commonly, these infections induce persistent pro-inflammatory cytokine production in the region where the tumor arises. Chronic production of inflammatory cell-derived reactive oxygen and nitrogen intermediates damages DNA and other biomolecules, progressively transforming normal tissue into malignant lesions [83,84]. Experimental evidence has shown that the leukocyte infiltrate plays a pivotal role in facilitating benign lesions to become more aggressive and turn into metastatic tumors [85,86]. At low to moderate levels, reactive intermediates can cause continual cellular damage without inducing excessive tissue necrosis. In addition, this damage stimulates leukocyte reparative activities, which can also promote malignant growth over the long term [6].

Although these chronic infections frequently lead to permanent malignant change, there are exceptions. Low grade [87], and occasionally high grade [88–90] mucosa-associated lymphoid tissue (MALT) lymphomas may regress following antibiotic treatment. These have primarily included MALT lymphomas of the stomach, but also those of the small and large bowel, bladder, larynx, lung, nasopharynx, salivary glands, spleen, and thyroid [74,91–

99]. To date, most antibiotic-regressive lymphomas have been associated with *H. pylori* infections, although some may be associated with other *Helicobacter* species [100], *Campylobacter jejuni* [101], hepatitis C virus (HCV) [98], or of undetermined infectious origin [92,102]. Similar evidence has been found for other benign and malignant tumors. For example, gastric adenomas may regress following removal of *H. pylori* [103]. Antiviral treatment of benign [104] and malignant [105] lesions caused by HPV may also regress. Thus, in these various tumors, when antimicrobial treatment removes the foreign pathogen, the stimulus for continued production of reactive intermediates by associated leukocytes is removed. Correspondingly, chronic growth-promoting leukocyte reparative activities also subside, facilitating tumor regression.

6. Mechanisms of tumor inhibition

A notable observation in malignant tumors is the considerable mass of tumor-infiltrating leukocytes (TILs) [106,107]. These are heterogeneous populations of cells, consisting of variable proportions of neutrophils, eosinophils, macrophages, fibroblasts, T and B cells, mast cells, and natural killer cells. Although the presence of these host inflammatory cells within or at the periphery of solid tumors has long been recognized, their biological and clinical significance has been the subject of mostly conflicting reports [106,108,109]. In view of their normally defensive role in vivo, leukocyte infiltration into tumors was originally believed to herald an immune response to the growing malignancy. However, recent studies suggest that immune cells play a very unexpected role [5,6].

Klebs, in the late 19th century, was one of the first authors to speculate that immune cells could actually stimulate cancer growth, suggesting that these cells had a “fructifying” influence that caused cancer cells to multiply [110].

Animals studies along these lines were first carried out by Jones and Rous [111]. In their early experimental studies, a variety of chemical, biological and inert materials were used to induce inflammation in the peritoneum of mice. Peritoneal tissue was subsequently inoculated with tumor cells and a much greater tendency for implantation was observed in mice with inflamed tissue over untreated animals [111]. Similarly, in studying a papilloma virus in chickens (i.e. Rous sarcoma virus), Rous emphasized that trauma to the site of inoculation was necessary for its establishment [112,113]. They concluded from these investigations that “the secondary localization of tumours at points of injury is referable to the presence at such points of a very cellular connective tissue which may come more readily than the normal to the support and nourishment of tumour cells” [111]. This “cellular connective tissue” following injury is typical of immune cell infiltration. In 1972, Haddow further developed this concept suggesting that tumors are analogous to unhealing wounds [114]. In this view, cells of the immune system, which are also involved in tissue repair [115], become attracted to these lesions, and assume their normal reparative activities such as expanding the vascular network and stimulating tissue regrowth [116,117]. Recent evidence increasingly supports the concept that naturally growing tumors progress with the assistance, rather than the antagonism, of the immune system [118–120]. Wounding triggers the release of a diverse array of chemokines that attract leukocytes and other connective tissue cells, which in turn mediate the repair process. Such signals decline as the wound heals. Much like wounded tissue, malignant cells also release chemokines to signal that increased oxygen and nutrients are required [121]. Yet, these signals only continue to intensify to support the ever-growing needs of the tumor. Leukocytes, particularly macrophages, are present in large numbers in many rapidly growing tumors [5,106,109]. Macrophages are abundant in regions of high tumor cell proliferation, where evidence of macrophage-induced tumor cell killing is rare or absent [122]. Macrophages are versatile and resilient phagocytes capable of prolonged survival in the acidic wound environment [122]. Moreover, macrophages contribute to the production, mobilization, activation and regulation of all immune cells as well as producing a range of vascular and cellular growth factors [123]. There is even evidence that monocyte/macrophages can differentiate into endothelial progenitor cells [124,125] and fibroblasts [106,109].

Tumor overexpression of macrophage chemokines has been associated with a poor prognosis [120]. In a mouse model study by Lin et al. [126], genetic depletion of the macrophage chemokine colony stimulating factor-1 (CSF-1) reduced macrophage tumor infiltration and was associated with a significant delay in tumor progression and metastasis. In contrast, tumor overexpression of CSF-1 increased macrophage density and enhanced malignancy [126]. Similarly, Robinson et al. [119] studied the effects of

chemokine receptor antagonist on tumor growth in mice. Daily treatment for 5 weeks with an antagonist to the leukocyte chemokine, RANTES, led to a significantly reduced tumor volume, weight and macrophage infiltration as compared to controls. Thus, the leukocyte inflammatory response aids in the initiation and progression of the malignancy, and chronic infections within the host represent a common stimulus of this persistent inflammation.

In contrast, acute infections alter the function of these subverted TILs, shifting the balance back towards the defensive arm. For example, Gabizon et al. [127] studied the influence of macrophages from normal and tumor-bearing mice on the growth of experimental tumors (fibrosarcoma, melanoma and lymphoma) in vivo. Both macrophage populations were found to stimulate tumor growth. However, when an acute infection was mimicked through exposure of macrophages to killed *Corynebacterium parvum*, macrophages were able to inhibit tumor growth in a dose-dependent manner. Although such stimulated macrophages can be tumoricidal, this state of activation for tumor cell killing is transient [128,129].

Spontaneous tumor regression has been observed in association with a wide range of infectious organisms including those of bacterial, fungal, viral, and protozoal origin [6]. This evidence suggests that an analogous general reaction to these widely divergent infectious agents is playing a role in this regression. The acute febrile response may be such a reaction, as it is a characteristic feature of the innate immune response to infection [130]. In cases of infection-associated spontaneous regression, such regressions are often observed during the acute febrile phase [7]. In contrast, when the febrile phase of the infection has subsided, residual tumor often recurs [6,7].

Fever suppression during infection with antipyretics or other means has been shown to significantly increase morbidity and mortality in animals relative to control animals without fever suppression [6,131]. Similar findings have been observed in humans [6,132]. Febrile temperatures have been shown to augment many functions of the immune system, including enhanced T cell stimulatory activity of dendritic cells, antigen uptake, activation-associated migration, maturation, and cytokine expression [133]. With respect to established tumors, immune cells have already infiltrated around and within the tumor mass. These tumor-infiltrating leukocytes could become non-specifically activated during a febrile infection. The simultaneous suspension of immune reparative functions and upregulation of cytotoxic properties could then induce tumor regression [6]. Furthermore, the fragile and tortuous nature of tumor vasculature compared to ordinary vessels [134] would make it more susceptible to febrile immunostimulated collapse, resulting in hemorrhagic necrosis of the dependent tumor mass.

In the delicate balance between reparative-derived growth stimulation and defensive-induced tumor regression, leukocytes may determine the outcome as to tumor

progression or regression. Thus, if leukocytes can fuel the progression from benign lesions to malignant tumors [85,86], their counter activation can be a means to cancer prevention. For example, there is increasing momentum to develop and study agents that can suppress inflammation as a means of preventing cancer. Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) have become a key focus of investigation due to their inhibitory effects on COX-1 and COX-2 enzymes [135]. Yet through such an approach, one may only be delaying the inevitable, and prolonged use of such agents is not without adverse effects. An alternative approach would be to stimulate rather than suppress the immune system [6,136]. For example, the findings of Kolmel et al. [137] have suggested that some vaccines may in fact decrease one's risk of dying from melanoma. In a cohort study of 542 melanoma patients followed from 1993 to 2002, hazard ratios (HR) were determined based upon previous vaccination with vaccinia [HR = 0.55, 95% CI 0.34–0.89] or Bacille Calmette-Guérin [HR = 0.75, 95% CI 0.30–1.86] or both [HR = 0.41, 95% CI 0.25–0.69]. Both vaccines consist of live attenuated pathogens. Similarly, previous case control studies by the same group [138,139] demonstrated that a history of vaccination either by vaccinia or BCG was associated with a significantly reduced risk of developing melanoma. Thus, these studies suggest that with respect to cancer, some vaccines may provide sufficient immunological stimulus to supplant the infections they prevent.

7. Conclusions

In contrast to many chronic infections that are known to be associated with an increased cancer risk, this review of epidemiological studies provided support for an antagonism between acute infections and cancer. Ironically, one of the case-control studies referred to was initiated to verify one investigator's impression that colds occurred less frequently in patients he saw with cancer than those with other diseases [62]. Thus, in agreement with Didot [13], since the time of Hippocrates nearly 2500 years ago, the antagonism between acute infections and malignant disease has been apparent. Unfortunately, although this association has long been noted, it is not generally well appreciated. Little credence is given to the febrile immune response in fighting infections—no less cancer [6].

In this respect, several avenues of investigation could be undertaken. First, prospective epidemiological studies are required for a more conclusive understanding of the nature of the acute infection/cancer association. Another consideration is the increasing use of drugs to suppress symptoms of the immune response during acute infections and how these drugs may affect the immune system and subsequent cancer risk. Antipyretics, decongestants, and antihistamines are all routinely used nonprescription drugs for respiratory and other infections. All of these drugs interfere with some component of the immune response. Yet,

there is evidence to suggest that some of these medications are not totally benign, and may increase morbidity and mortality from the infections they are used to remedy [6,132,140]. Whether their repeated use during infections could influence subsequent cancer risk remains to be determined. Some recent studies have suggested that antipyretic use is associated with an increased risk of non-Hodgkin's lymphoma [141,142], but more research is needed. Perhaps in childhood fever, the immediate use of antipyretics should be reconsidered in light of these findings.

Finally, many new vaccines have been introduced in recent years to counter common and some less common infectious diseases. The higher incidence of some cancers amongst individuals of a higher socioeconomic status may reflect the negative aspects of reduced exposure to acute infections. In contrast, the work by Kolmel et al. [137–139] suggests that at least some vaccines may be beneficial with respect to subsequent cancer risk. How changes in infectious disease rates will alter cancer incidence remains to be seen, but should remain an area of intense study.

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Exhibit R



Cancer Stat Facts: Ovarian Cancer

(<https://seer.cancer.gov>)

Statistics at a Glance

At a Glance

Estimated New Cases in 2019	22,530
-----------------------------	--------

% of All New Cancer Cases	1.3%
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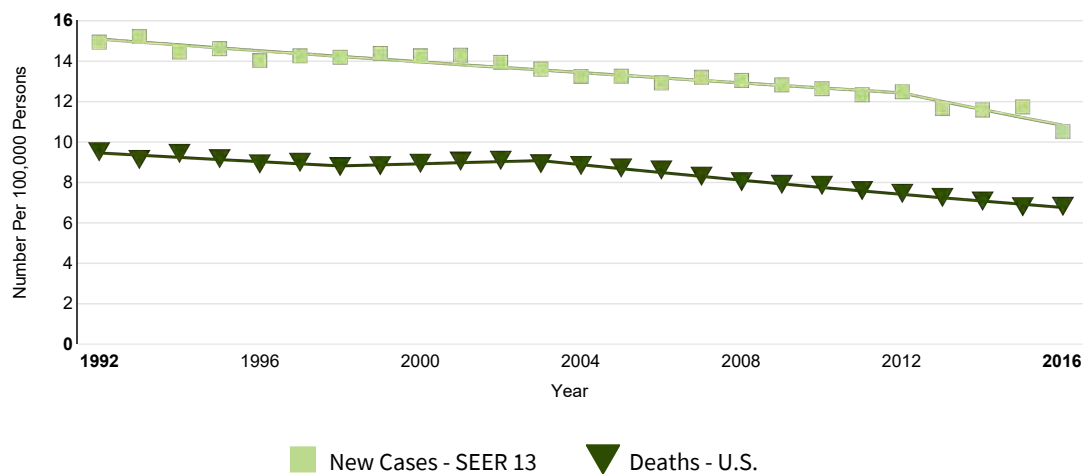
Estimated Deaths in 2019	13,980
--------------------------	--------

% of All Cancer Deaths	2.3%
------------------------	------

Percent Surviving 5 Years

47.6%

2009-2015



Modeled trend lines were calculated from the underlying rates using the Joinpoint Trend Analysis Software.

[View Data Table](#)

Number of New Cases and Deaths per

100,000: The number of new cases of ovarian cancer was 11.4 per 100,000 women per year.

The number of deaths was 7.0 per 100,000 women per year. These rates are age-adjusted and based on 2012-2016 cases and deaths.

Lifetime Risk of Developing Cancer:

Approximately 1.3 percent of women will be diagnosed with ovarian cancer at some point during their lifetime, based on 2014-2016 data.

Prevalence of This Cancer: In 2016, there were an estimated 229,875 women living with ovarian cancer in the United States.



Did you know?

Rates of new diagnoses and deaths from ovarian cancer are declining.

Survival Statistics

Number of New Cases and Deaths

Trends in Rates

More About This Cancer

These stat facts focus on population statistics that are based on the U.S. population. Because these statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient. To see tailored statistics, browse the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). To see statistics for a specific state, go to the State Cancer Profiles (<https://seer.cancer.gov><https://statecancerprofiles.cancer.gov/>).

The statistics presented in these stat facts are based on the most recent data available, most of which can be found in the SEER Cancer Statistics Review (<https://seer.cancer.gov><https://seer.cancer.gov/csr/>). In some cases, different year spans may be used. Estimates for the current year are based on past data.

Cancer is a complex topic. There is a wide range of information available. These stat facts do not address causes, symptoms, diagnosis, treatment, follow-up care, or decision making, although links are provided to information in many of these areas.

Exhibit S



Contents lists available at ScienceDirect

Atherosclerosis

journal homepage: www.elsevier.com/locate/atherosclerosis

Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study



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ABSTRACT

Objective: Although it has been suggested that exposure to infections during childhood could decrease risk of atherosclerotic cardiovascular disease (CVD), the evidence is scarce. We investigated the association of measles and mumps with CVD.

Methods: 43,689 men and 60,147 women aged 40–79 years at baseline (1988–1990) completed a life-style questionnaire, including their history of measles and mumps, and were followed until 2009. Histories of infections were categorized as having no infection (reference), measles only, mumps only, or both infections. Hazard ratios (HR) for mortality from CVD across histories of infections were calculated. **Results:** Men with measles only had multivariable HR (95% confidence interval) of 0.92 (0.85–0.99) for total CVD, those with mumps only had 0.52 (0.28–0.94) for total stroke and 0.21 (0.05–0.86) for hemorrhagic stroke, and those with both infections had 0.80 (0.71–0.90) for total CVD, 0.71 (0.53–0.93) for myocardial infarction, and 0.83 (0.69–0.98) for total stroke. Women with both infections had 0.83 (0.74–0.92) for total CVD and 0.84 (0.71–0.99) for total stroke. We also compared subjects with measles only or mumps only (reference) and those with both infections. Men with both infections had 0.88 (0.78–0.99) for total CVD. Women with both infections had 0.85 (0.76–0.94) for total CVD, 0.79 (0.67–0.93) for total stroke, 0.78 (0.62–0.98) for ischemic stroke and 0.78 (0.62–0.98) for hemorrhagic stroke.

Conclusions: Measles and mumps, especially in case of both infections, were associated with lower risks of mortality from atherosclerotic CVD.

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1. Introduction

It has been suggested that infection can impact atherosclerotic cardiovascular disease (CVD) either deleteriously or positively [1]. The former proposes that inflammation caused by chronic infections with pathogens such as *Chlamydia pneumoniae* and herpes simplex virus type I can accelerate atherosclerosis [1–6]. The latter suggests that infections suffered during childhood can protect from atherosclerosis [1]. The 'hygiene hypothesis' is a possible mechanism underlying this effect [1,7,8]. Improved hygiene decreases the opportunities for infections, which are necessary for normal development of the immune system. Weakened immune systems

lead to decreased production, as well as inactivation, of regulatory T cells, which control the balance of T helper cell types, Th1 and Th2. As a result, inflammation at the arterial wall is not well controlled, leading to the development of atherosclerosis. Therefore, people with a history of infections may have a lower risk of CVD, especially atherosclerotic diseases such as stroke and myocardial infarction, compared to those without previous infections. However, to the best of our knowledge, only one previous study, which used a retrospective design and had a small number of participants, has suggested that viral or bacterial infections could protect against CVD [1].

To confirm the protective effect of infections against CVD, this study prospectively examined whether a history of measles and mumps, diseases typically seen in children, alters the risk of mortality from CVD before the era of measles, mumps, and rubella (MMR) vaccination [1,9].

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2. Methods

2.1. Study population

The details of the Japan Collaborative Cohort (JACC) Study for Evaluation of Cancer Risks have been described previously [10]. Briefly, this study conducted a baseline survey from 1988 through 1990 in 45 areas in Japan. Participants completed self-administered questionnaires on their lifestyle and medical history with respect to previous CVD and cancer. The participants comprised 110,585 subjects (46,395 men and 64,190 women) aged 40–79 years. Participants were not vaccinated for measles and mumps, as the MMR vaccine was not introduced in Japan until 1989 [11]. This study excluded 6749 subjects (2706 men and 4043 women) due to missing information on their history of measles and mumps infections. Therefore, a total of 103,836 subjects (43,689 men and 60,147 women) were included in the study. The ethics committees of the Nagoya University School of Medicine and the Osaka University Graduate School of Medicine approved the present study.

2.2. Mortality surveillance

This study conducted systematic mortality surveillance by reviewing death certificates, which were transferred to their respective public health centers. After that, mortality data were gathered at the Ministry of Health and Welfare, where the underlying causes of death were coded for the National Vital Statistics according to the International Classification of Diseases. All deaths within the cohort were ascertained by death certificates from public health centers. Subjects who died after they had moved from their original community were treated as censored cases. The participants were followed up until the end of 2009. In addition to mortality from total CVD, follow-up endpoints included mortality from total stroke, ischemic stroke, hemorrhagic stroke, and myocardial infarction. Death from total CVD was defined as ICD-10 codes I00–I99, total stroke as I60–I69, ischemic stroke as I63 or I69.3, hemorrhagic stroke as I60–I62 or I69.0–I69.2, and myocardial infarction as I21–I23.

2.3. Main exposure: History of measles and mumps

Subjects were asked to provide information about their history of measles and mumps. Specifically, they were asked in the questionnaires, 'Have you ever had the following infectious diseases?: Measles, Mumps'. First, to examine the association of measles and mumps with CVD, participants were classified into the following four groups for comparison: those without a history of measles or mumps (reference group), those with a history of measles only, those with mumps only, and those with a history of both measles and mumps. In addition, to examine whether there is an additional decrease in risk by increased number of infections, we compared participants with a history of a single infection (measles only or mumps only) and those with a history of a double infection (both measles and mumps).

2.4. Potential confounding factors

Potential confounding factors were measured via self-reporting at baseline. They included age (years), body mass index (sex-specific quintiles), history of hypertension (yes or no), history of diabetes (yes or no), history of CVD (coronary heart disease and stroke), family history of CVD (yes or no), alcohol intake (never, ex-drinker, or current drinker with an ethanol intake of 1–22, 23–45, 46–48, or ≥ 69 g per day), smoking status (never, ex-smoker, or current smoker of 1–19 or ≥ 20 cigarettes per day), walking

frequency (rarely, 30, 30–60, or ≥ 60 min per day), participation in sports (rarely, 1–2, 3–4, or ≥ 5 h per week), perceived mental stress (low, medium, or high), and education (elementary school, junior high school, high school, and college or higher).

2.5. Statistical analysis

The person-years of follow-up were calculated from the baseline in 1988–1990 to the first endpoint: death, moving from the community, or the end of follow-up. Multiplicative interactions with sex were tested using a cross-product term. Since there were statistically significant interactions between a history of infections and sex in relation to total stroke and hemorrhagic stroke, sex-specific analysis was conducted. Sex-specific mean values and the prevalence of selected factors were calculated and compared among the four groups using ANOVA and χ^2 tests, respectively. Sex-specific Kaplan–Meier's survival curves for men and women were constructed. Sex-specific hazard ratios (HRs) and their 95% confidence intervals (CIs) of mortality outcomes were calculated after adjustment for age and other potential confounding factors using Cox proportional hazard models. The proportional hazards assumption was tested and was not violated. SAS version 9.3 software (SAS Institute Inc., Cary, NC) was used for statistical analyses. All statistical tests were two-tailed, with values of $P < 0.05$ regarded as significant.

3. Results

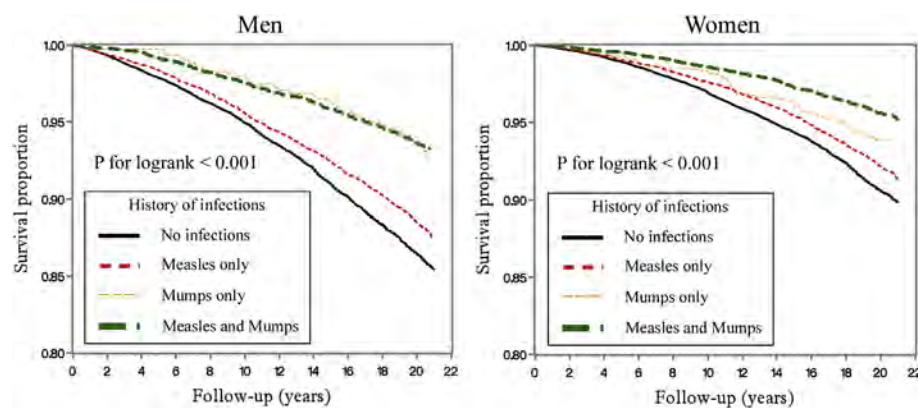
Table 1 shows the baseline characteristics with respect to a history of measles or mumps. The higher the number of infections (no infection, measles only or mumps only, and both measles and mumps) in a participant's history was, the younger and less hypertensive both men and women were, the less often they took part in sports, and the higher education level they had. Compared with participants without a history of measles or mumps, those with a history of measles or mumps were more likely to have a family history of CVD and high perceived mental stress. In addition, as for men, the higher the number of infections was, the higher body mass index and the lower prevalence of a history of CVD they had. As for women, those with a history of infections were more likely to have a history of CVD than those without a history of infections.

During 1,690,123 person-years of follow-up of 103,836 subjects (43,689 men and 60,147 women), this study documented 7816 deaths from total CVD (4029 men and 3787 women), 3396 from total stroke (1729 men and 1667 women), 1955 from ischemic stroke (1062 men and 893 women), 1335 from hemorrhagic stroke (612 men and 723 women), and 1212 from myocardial infarction (694 men and 518 women).

Fig. 1 presents the survival curves for each category. The larger decline in survival rate was observed for both men and women without a history of infections than those with a history of infections. Table 2 shows sex-specific, age-adjusted, and multivariable HRs (95% CI) for cause-specific mortality according to infection history. In general, compared with participants without a history of infections, the hazard ratios of cause-specific mortality in those with a history of measles or mumps were likely to decrease. Men and women with measles or mumps displayed significantly lower risks (95% CI) than those without any infection after adjustment for potential confounding factors. It made no difference whether or not a history of CVD was included in potential confounding factors. Men with a history of measles only had hazard ratios of 0.92 (0.85–0.99) for total CVD, those with a history of mumps only had hazard ratios of 0.52 (0.28–0.94) for total stroke and 0.21 (0.05–0.86) for hemorrhagic stroke, and those with a history of both measles and mumps had hazard ratios of 0.80 (0.71–0.90) for

Table 1
Baseline characteristics according to history of Measles or Mumps infection.

History of measles or mumps infection	Men				P Value	Women				P Value
	None	Measles only	Mumps only	Measles and mumps		None	Measles only	Mumps only	Measles and mumps	
No. at risk	21,245	14,671	730	7043	–	24,950	21,202	1256	12,739	–
Age, years	58.7	57.7	54.0	53.0	<0.001	59.0	58.0	55.9	54.4	<0.001
Body mass index, kg/m ²	22.6	22.6	22.7	22.9	<0.001	22.9	23.0	22.9	22.9	0.419
History of hypertension, %	22.5	21.9	19.3	18.4	<0.001	24.2	23.9	23.1	20.6	<0.001
History of diabetes, %	7.4	6.5	7.9	6.0	<0.001	4.7	3.8	5.1	3.7	<0.001
History of cardiovascular disease, %	4.7	4.7	3.8	3.9	0.016	3.1	3.5	5.8	3.3	<0.001
Family history of cardiovascular disease, %	41.7	44.8	44.4	43.8	<0.001	41.6	45.0	44.2	45.6	<0.001
Ethanol intake, g/day	34.4	34.0	32.7	34.5	0.207	10.9	10.4	10.7	9.8	0.080
Current smoker, %	53.2	52.7	54.2	53.7	0.464	5.8	4.7	5.6	5.7	<0.001
Walking ≥1 h/day, %	47.7	50.5	45.6	49.6	<0.001	50.0	51.2	47.7	51.9	0.002
Sports ≥5 h/week, %	7.7	7.2	6.2	5.9	<0.001	5.3	4.7	4.0	3.6	<0.001
High perceived mental stress, %	20.0	21.5	34.5	30.2	<0.001	17.7	18.9	23.4	24.6	<0.001
College or higher education, %	15.8	16.8	21.6	22.2	<0.001	8.1	9.8	12.5	13.3	<0.001

**Fig. 1.** Kaplan-Meire survival curves of mortality from total cardiovascular disease according to the history of infections among men and women.**Table 2**
Age-adjusted and multivariable hazard ratios (HR) and 95% Confidential Intervals (CI) for Cause-specific mortality according to history of measles or mumps.

History of measles or mumps	Men				Women			
	None	Measles only	Mumps only	Measles and mumps	None	Measles only	Mumps only	Measles and mumps
No. at risk	21,245	14,671	730	7043	24,950	21,202	1256	12,739
Person-years	326,940	236,327	11,802	116,443	411,090	358,358	19,963	209,207
Total stroke, n	946	613	11	159	803	640	31	193
Age-adjusted HR (95% CI)	1.00	0.97 (0.87–1.07)	0.52 (0.29–0.94)	0.83 (0.70–0.98)	1.00	1.07 (0.96–1.18)	1.24 (0.86–1.77)	0.85 (0.73–0.99)
Multivariable HR (95% CI) ^a	1.00	0.95 (0.85–1.06)	0.52 (0.29–0.94)	0.83 (0.70–0.99)	1.00	1.06 (0.95–1.19)	1.27 (0.88–1.82)	0.85 (0.72–0.99)
+ history of CVD ^b	1.00	0.95 (0.85–1.06)	0.52 (0.28–0.94)	0.83 (0.69–0.98)	1.00	1.06 (0.94–1.19)	1.22 (0.87–1.75)	0.84 (0.71–0.99)
Ischemic stroke, n	588	375	8	91	456	334	12	91
Age-adjusted HR (95% CI)	1.00	0.98 (0.86–1.11)	0.67 (0.33–1.35)	0.85 (0.68–1.06)	1.00	1.03 (0.89–1.18)	0.93 (0.52–1.64)	0.80 (0.64–1.00)
Multivariable HR (95% CI) ^a	1.00	0.98 (0.85–1.13)	0.70 (0.35–1.42)	0.88 (0.70–1.11)	1.00	1.05 (0.90–1.22)	0.98 (0.55–1.75)	0.81 (0.64–1.03)
+ history of CVD ^b	1.00	0.98 (0.85–1.13)	0.70 (0.35–1.41)	0.87 (0.69–1.10)	1.00	1.04 (0.89–1.22)	0.93 (0.52–1.65)	0.81 (0.64–1.02)
Hemorrhagic stroke, n	324	221	2	65	325	284	18	96
Age-adjusted HR (95% CI)	1.00	0.98 (0.82–1.16)	0.23 (0.06–0.93)	0.81 (0.62–1.06)	1.00	1.12 (0.95–1.31)	1.59 (0.99–2.55)	0.90 (0.71–1.13)
Multivariable HR (95% CI) ^a	1.00	0.91 (0.75–1.09)	0.21 (0.05–0.85)	0.76 (0.58–1.01)	1.00	1.08 (0.91–1.29)	1.58 (0.97–2.56)	0.86 (0.68–1.10)
+ history of CVD ^b	1.00	0.91 (0.75–1.09)	0.21 (0.05–0.86)	0.76 (0.57–1.00)	1.00	1.08 (0.90–1.29)	1.54 (0.95–2.49)	0.86 (0.67–1.09)
Myocardial infarction, n	378	248	5	63	275	171	8	64
Age-adjusted HR (95% CI)	1.00	0.96 (0.81–1.12)	0.54 (0.22–1.31)	0.74 (0.56–0.96)	1.00	0.85 (0.70–1.03)	0.97 (0.48–1.96)	0.85 (0.64–1.12)
Multivariable HR (95% CI) ^a	1.00	0.92 (0.77–1.09)	0.52 (0.22–1.27)	0.71 (0.54–0.94)	1.00	0.87 (0.71–1.08)	1.01 (0.50–2.06)	0.85 (0.63–1.13)
+ history of CVD ^b	1.00	0.92 (0.77–1.09)	0.52 (0.22–1.27)	0.71 (0.53–0.93)	1.00	0.87 (0.71–1.07)	0.99 (0.48–2.00)	0.84 (0.63–1.13)
Total cardiovascular disease, n	2243	1383	38	365	1913	1378	57	439
Age-adjusted HR (95% CI)	1.00	0.92 (0.86–0.99)	0.76 (0.55–1.04)	0.80 (0.71–0.89)	1.00	0.97 (0.91–1.05)	0.98 (0.75–1.27)	0.83 (0.75–0.92)
Multivariable HR (95% CI) ^a	1.00	0.92 (0.86–0.99)	0.75 (0.55–1.04)	0.81 (0.72–0.91)	1.00	0.98 (0.91–1.06)	1.01 (0.78–1.32)	0.83 (0.75–0.93)
+ history of CVD ^b	1.00	0.92 (0.85–0.99)	0.75 (0.54–1.04)	0.80 (0.71–0.90)	1.00	0.97 (0.90–1.05)	0.97 (0.75–1.27)	0.83 (0.74–0.92)

^a Adjusted for age, body mass index, history of hypertension, history of diabetes, family history of CVD, alcohol intake, energy intake, smoking status, walking, sports, perceived mental stress and education.^b Further adjustment for history of CVD. CVD indicates cardiovascular disease.

total CVD, 0.83 (0.69–0.98) for total stroke, and 0.71 (0.53–0.93) for myocardial infarction. Women with a history of both measles and mumps had hazard ratios of 0.83 (0.74–0.92) for total CVD and 0.84 (0.71–0.99) for total stroke.

To examine whether there is an additional decrease in risk by increased number of infections, participants with a history of a single infection (measles only or mumps only) and those with a history of a double infection (both measles and mumps) were compared (Table 3). Both men and women with a history of a double infection were likely to have lower risks of mortality from most diseases than those with a history of a single infection. Men with a history of a double infection showed significantly higher risks of age-adjusted mortality from total CVD than those with a history of a single infection. After adjustment for potential confounding factors, the associations were still statistically significant. The respective multivariable hazard ratios (95% CI) were 0.88 (0.78–0.99) for total CVD. As for women, we observed, compared with women with a history of a single infection, those with a history of a double infection had decreased risks of age-adjusted mortality from total CVD, total stroke, ischemic stroke, and hemorrhagic stroke, respectively. Further adjustment for potential confounding factors did not alter the relations between the number of a history of infections and mortality risks. The multivariable hazard ratios (95% CI) were as follows: 0.85 (0.76–0.94) for total CVD; 0.79 (0.67–0.93) for total stroke; 0.78 (0.62–0.98) for ischemic stroke; 0.78 (0.62–0.98) for hemorrhagic stroke.

4. Discussion

This prospective cohort study of middle-aged Japanese men and women found the following two things. First, both subjects with a history of measles and those with a history of mumps had a lower risk of mortality from CVD than those without a history of infections. Second, a higher number of infections was associated with a lower risk of mortality from CVD. To the best of our knowledge, this is the first population-based cohort study to prospectively investigate the positive impact of infections on CVD in both men and women.

A history of infections decreased the risk of mortality from atherosclerotic CVD. A mechanism that may explain this is the induction of regulatory T cells following acquisition of infection, and suppression of inflammation in the arterial wall, which prevents

the progression of atherosclerosis [1,7,8]. Measles and mumps infections demonstrated this protective effect in the current study. Although reports indicate that measles infection has an immunosuppressive effect [12] and induces regulatory T cells via its nucleoprotein [8], there are no similar effects reported for mumps. In addition, a previous study has suggested that other infectious diseases, such as varicella and scarlet fever, can decrease the risk of CVD; however, the study was retrospective and included only a small number of subjects [1]. Therefore, other infections could also have a protective effect against CVD, similar to the effect shown in this study for measles and mumps. However, chronic infections, such as *C. pneumonia* and herpes simplex virus type I, as well as common viral respiratory infections, are unlikely to be purveyors of a protective effect [2–6,13].

We observed that a higher number of infections was associated with a lower risk of mortality from CVD. This result can also be explained by the 'hygiene hypothesis'. The more opportunities for infections during childhood produce and activate more regulatory T cells, which leads to the suppression of atherosclerosis.

In the current study, men with a history of infections were less likely to have a history of CVD at baseline than those without a history of infections, which could support our major findings. On the other hand, women with a history of infections were more likely to have a history of CVD than those without a history of infections. This seems incompatible with our major findings. One possible explanation for this is that since before the baseline survey more women without a history of infections already died from CVD than those with a history of infections, those without a history of infections were less likely to have a history of CVD at baseline. Another possible explanation is information bias (misclassification) on the assessment of a history of CVD or infections. We found no significant interactions between a history of infections and a history of CVD in relation to any outcomes (data not shown), and obtained almost similar results of the adjusted models before and after including a history of CVD in confounding factors. In addition, even if some women with a history of CVD (women with a high risk of mortality from CVD) were misclassified into not a group without a history of infections (a group with a higher risk of mortality from CVD) but groups with a history of infections (groups with a lower risk of mortality from CVD), then the association between a history of infections and the risk of mortality from CVD would approach null. Therefore, we assume that the possible information biases on

Table 3

Age-adjusted and multivariable^a Hazard Ratios (HR) and 95% Confidential Intervals (CI) for cause-specific mortality according to history of single vs. double infection.

History of measles or mumps	Men		Women	
	Single (measles only or mumps only)	Double (measles and mumps)	Single (measles only or mumps only)	Double (measles and mumps)
No. at risk	15,401	7043	22,458	12,739
Person-years	248,129	116,443	378,321	209,207
Total stroke, n	624	159	671	193
Age-adjusted HR (95% CI)	1.00	0.87 (0.73–1.04)	1.00	0.79 (0.68–0.93)
Multivariable HR (95% CI)	1.00	0.89 (0.74–1.06)	1.00	0.79 (0.67–0.93)
Ischemic stroke, n	383	91	346	91
Age-adjusted HR (95% CI)	1.00	0.88 (0.70–1.18)	1.00	0.78 (0.62–0.99)
Multivariable HR (95% CI)	1.00	0.90 (0.71–1.13)	1.00	0.78 (0.62–0.98)
Hemorrhagic stroke, n	223	65	302	96
Age-adjusted HR (95% CI)	1.00	0.85 (0.65–1.13)	1.00	0.79 (0.63–0.99)
Multivariable HR (95% CI)	1.00	0.86 (0.65–1.14)	1.00	0.78 (0.62–0.98)
Myocardial infarction, n	253	63	179	64
Age-adjusted HR (95% CI)	1.00	0.78 (0.59–1.03)	1.00	0.99 (0.75–1.32)
Multivariable HR (95% CI)	1.00	0.78 (0.59–1.03)	1.00	0.96 (0.72–1.28)
Total cardiovascular disease, n	1421	365	1435	439
Age-adjusted HR (95% CI)	1.00	0.87 (0.78–0.98)	1.00	0.85 (0.77–0.95)
Multivariable HR (95% CI)	1.00	0.88 (0.78–0.99)	1.00	0.85 (0.76–0.94)

^a Adjusted for age, body mass index, history of hypertension, history of diabetes, history of cardiovascular disease, family history of cardiovascular diseases, alcohol intake, energy intake, smoking status, walking, sports, perceived mental stress and education.

the assessment of a history of CVD or infections did not have enough influence to change the results.

Together with previous research [8,14], this study demonstrates the importance of the immune system's impact on CVD. Stimulation of immune function, as in vaccination, may be a novel treatment for CVD in the future, though whether conventional vaccinations have enough power to induce regulatory T cells is unclear.

Strengths of this study include its prospective design, long follow-up duration, and the inclusion of a large number of participants. In addition, setting not only total CVD but also cause-specific mortality as endpoints were useful for understanding the impact of infections on CVD.

Some limitations need to be addressed. Firstly, the assessment of measles and mumps infections was based on self-reporting. However, measles and mumps were significant problems in the era before MMR vaccination in Japan, meaning that these diseases were likely to be accurately recalled. Although we cannot negate such information biases as mentioned above, this study assumes that those biases did not significantly influence the results. Secondly, the study did not obtain information on the age that participants suffered from measles or mumps infections. However, the majority had measles or mumps during their childhood, in the era before MMR vaccination [1,9]. Thirdly, this study only examined exposure to measles and mumps infections, although other infections may have unknown influences on the risk of mortality from CVD. Despite this possibility, the fact remains that the more infections people acquire during childhood, the lower their risk of mortality from CVD, possibly due to the induction of regulatory T cells. Finally, this study used mortality data as endpoints, which may have led to misclassifications in the diagnosis of CVD. However, previous validation studies confirm the validity of using death certificate diagnoses for these outcomes due to the widespread use of computed tomography, magnetic resonance imaging, electrocardiography, and cardiac enzyme examinations [15,16].

In conclusion, measles and mumps infections were associated with decreased risks of mortality from CVD. In addition, people with a history of more infections were likely to have lower risks of mortality from CVD. Further studies are needed to assess whether other infections seen typically during childhood have similar associations with mortality from CVD.

Conflict of interest

All authors have no conflict of interest or financial disclosures to declare.

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Exhibit T

Heart Disease Facts

As plaque builds up in the arteries of a person with heart disease, the inside of the

arteries begins to narrow, which lessens or blocks the flow of blood. Plaques can also rupture (break open) and when they do a blood clot can form on the plaque, blocking the flow of blood.

Learn more about heart disease and its risk factors. It's important for everyone to [know the facts about heart disease Cdc-pdf](#)

[\[PDF-243K\]](#).

Heart Disease in the United States

- About **610,000 people** die of heart disease in the United States every year—that's **1 in every 4 deaths**.¹
- Heart disease is the leading cause of death for both men and women. **More than half** of the deaths due to heart disease in 2009 were in men.¹
- [Coronary heart disease](#) (CHD) is the most common type of heart disease, killing over **370,000 people** annually.¹
- Every year about **735,000 Americans** have a [heart attack](#). Of these, 525,000 are a first heart attack and 210,000 happen in people who have already had a heart attack.²

Heart Disease Deaths Vary by Race and Ethnicity

Heart disease is the leading cause of death for people of most ethnicities in the United States, including African Americans, Hispanics, and whites. For American Indians or Alaska Natives and Asians or Pacific Islanders, heart disease is second only to cancer. Below are the percentages of all deaths caused by heart disease in 2008, listed by ethnicity.⁴

Race of Ethnic Group	% of Deaths
American Indians or Alaska Natives	18.4
Asians or Pacific Islanders	22.2
Non-Hispanic Blacks	23.8
Non-Hispanic Whites	23.8
All	23.5

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Early Action is Important for Heart Attack

Heart Attack

Know the warning [signs and symptoms of a heart attack](#) so that you can act fast if you or someone you know might be having a heart attack. The chances of survival are greater when emergency treatment begins quickly.

- In a 2005 survey, most respondents—92%—recognized chest pain as a symptom of a heart attack. **Only 27%** were aware of all major symptoms and knew to call 9-1-1 when someone was having a heart attack.⁵
- **About 47%** of sudden cardiac deaths occur outside a hospital. This suggests that many people with heart disease don't act on early warning signs.⁶

Heart attacks have several **major warning signs** and symptoms:

- Chest pain or discomfort.
- Upper body pain or discomfort in the arms, back, neck, jaw, or upper stomach.
- Shortness of breath.
- Nausea, lightheadedness, or cold sweats.

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Americans at Risk for Heart Disease

[High blood pressure](#), [high cholesterol](#), and smoking are key [risk factors](#) for heart disease. About **half of Americans** (47%) have at least one of these three risk factors.⁷

Several other medical conditions and lifestyle choices can also put people at a higher risk for heart disease, including:

- Diabetes
- Overweight and obesity
- Poor diet
- Physical inactivity
- Excessive alcohol use

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CDC Fact Sheets Related to Heart Disease

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Exhibit U

Open forum

Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy[☆]

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Abstract

To investigate the association between non-Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL), and exposure to childhood diseases, we analyzed an Italian case-control study that included 225 histologically-confirmed incident cases of NHL, 62 HL cases, and 504 controls. After adjusting for confounding factors, all examined childhood diseases were negatively associated with HL. Measles was negatively associated with NHL, particularly follicular B-cell NHL. Our findings provide additional support to the hypothesis that infections by most common childhood pathogens may protect against HL or, at least, be correlated with some other early exposure, which may lower the risk of HL in adulthood. In addition, our study shows that measles may provide a protective effect against NHL.

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Keywords: Non-Hodgkin lymphoma (NHL); Hodgkin lymphoma (HL); Childhood diseases; Case-control study; Immunostimulation

1. Introduction

In most developed countries, Hodgkin lymphoma (HL) incidence has been stable, while that of non-Hodgkin lymphoma (NHL) has doubled over the past two decades [1,2]. The risk for some lymphomas is known to increase following exposure to certain viral or bacterial infections [2,3]. The only virus, thus far, established to be causally related to HL is the Epstein-Barr virus (EBV), with an approximately 40% attributable fraction [1,4] and the demonstration

that EBV genomes were present and expressed in the HD tumor cells (Reed-Sternberg cells) of a proportion of cases provided an important new understanding of the biology of the disease [5,6]. For several infectious agents (HIV, HHV8, HTLV, HCV, and *Helicobacter pylori*) [2,7–16], on the contrary, exist only indirect evidence of positive association due to the capacity to elude the immune system [17]. The childhood infections may have the opposite (protective) effect on lymphoma risk because of a different age of infection and/or less severe infections. In fact since 1988 some studies reported a potential protective effect of measles and other childhood diseases for lymphoma and multiple myeloma [7–9,18]. However, the etiology of most lymphomas is still unknown.

To further explore this topic, we investigated the potential association between NHL, HL, and a history of childhood diseases and mononucleosis using data from an Italian case-control study on lymphomas carried out in the province of

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Pordenone, northeast Italy, and in the city of Naples, southern Italy [13,14].

2. Material and methods

Between January 1999 and July 2002, we conducted a hospital-based case-control study in the province of Pordenone (northeast Italy) and in Naples (southern Italy). Details on study design are described elsewhere [13,14]. Briefly, the present report looks at 225 histologically-confirmed incident NHL cases and 62 HL cases, aged 18 years or more. Controls were 504 inpatients admitted to the same hospitals as those with the lymphomas for a wide spectrum of acute conditions. Specifically excluded from the control group were patients whose hospital admission was the result of malignant diseases, conditions related to alcohol and tobacco consumption, or hepatitis viruses. Hematological, allergic, and autoimmune diseases were also excluded. Co morbidity for the diseases listed above was not, however, a criterion for exclusion.

Histological specimens were classified according to the International Classification of Diseases for Oncology, which was updated to include categories in the Revised European-

American Lymphoma (REAL)/World Health Organization (WHO) classification [19].

All cases and controls were HIV-negative at HIV test, which was part of their routine management.

The interviews were conducted by means of a structured questionnaire, covering socio-demographic indicators, personal characteristics, and habits. In addition, the questionnaire included medical history and age at onset of the primary childhood infections. Cases were not individually matched to controls but they were comparable according to age and gender.

Adjusted ORs and corresponding 95% CIs were calculated by means of unconditional multiple logistic regression, including age (in 5-year groups plus a term for age as a continuous variable), gender, center, education, and place of birth. Individuals who reported mononucleosis and childhood diseases were compared with those who did not have these diseases.

3. Results

Education was negatively associated with HL (OR=0.4, in the highest tertile compared to the lowest, 95% CI:

Table 1

Distribution of 225 cases of non-Hodgkin lymphoma (NHL), 62 cases of Hodgkin lymphoma (HL), and 504 controls, odds ratios (OR) and corresponding 95% confidence intervals (CI)^a by selected socio-demographic factors (Italy, 1999–2002)

	Controls		NHL		OR	(95% CI)	HL		OR	(95% CI)
	No.	(%)	No.	(%)			No.	(%)		
Gender										
Males	341	(67.7)	120	(53.3)			33	(53.2)		
Females	163	(32.3)	105	(46.7)			29	(46.8)		
Age (years)										
<45	104	(20.6)	47	(20.9)			50	(80.7)		
45–64	177	(35.1)	107	(47.6)			10	(16.1)		
≥65	223	(44.3)	71	(31.6)			2	(3.2)		
Study center										
Aviano/Pordenone	280	(55.6)	127	(56.4)			37	(59.7)		
Naples	224	(44.4)	98	(43.6)			25	(40.3)		
Education (years)										
<7	251	(49.8)	97	(43.1)	1 ^c		12	(19.4)	1 ^c	
7–11	127	(25.2)	69	(30.7)	1.4	(0.9–2.1)	27	(43.6)	0.7	(0.3–1.8)
≥12	126	(25.0)	59	(26.2)	1.2	(0.8–1.8)	23	(37.1)	0.4	(0.1–1.0)
Place of birth										
North	248	(49.2)	98	(43.6)	1 ^c		23	(37.1)	1 ^c	
South	256	(50.8)	127	(56.4)	2.1	(1.2–3.5)	39	(62.9)	1.3	(0.5–3.3)
Younger siblings^b										
0	164	(32.5)	78	(34.7)	1 ^c		24	(38.7)	1 ^c	
1–2	230	(45.6)	97	(43.1)	0.9	(0.6–1.3)	28	(45.2)	0.9	(0.5–1.9)
≥3	110	(21.8)	50	(22.2)	1.1	(0.7–1.7)	10	(16.1)	1.4	(0.5–3.7)
Older siblings^b										
0	162	(32.1)	82	(36.4)	1 ^c		20	(36.4)	1 ^c	
1–2	226	(44.8)	106	(47.1)	0.9	(0.6–1.3)	26	(41.9)	0.8	(0.4–1.6)
≥3	116	(23.0)	37	(16.4)	0.6	(0.4–1.0)	16	(25.8)	1.2	(0.5–2.9)

^a Estimated from unconditional logistic regression adjusted for gender, age, center, education, and place of birth when appropriate.

^b The sum does not add up to the total because of some missing value.

^c Reference category.

0.1–1.0), but not with NHL (OR = 1.2; 95% CI: 0.7–1.8); while place of birth (Southern Italy versus Northern Italy) demonstrated an association only to NHL risk (OR = 2.1; 95% CI: 1.2–3.6). No difference emerged between cases (both NHL and HL) and controls based on number of younger siblings. However, a negative association (OR = 0.6; 95% CI: 0.4–1.0) did emerge for NHL only when there were three or more older siblings (Table 1).

Table 2 shows the relationship between lymphomas and a history of mononucleosis and/or childhood diseases. NHL showed a negative association with measles (OR = 0.6, 95% CI: 0.5–0.9); other childhood infections showed no association with NHL.

HL was negatively associated with all considered childhood diseases (Table 2). The significant ORs were for measles (OR 0.5, 95% CI: 0.2–0.7) and chickenpox (OR 0.5, 95% CI: 0.2–0.9), border-line values were found for parotitis (OR 0.6), rubella (OR 0.5), pertussis (OR 0.5), and scarlet fever (OR 0.2).

The OR among individuals who reported a history of three or more childhood diseases was 0.6 (95% CI: 0.4–1.0) for

NHL and 0.2 (95% CI: 0.1–0.6) for HL, when compared to subjects who reported no disease. Findings were similar when analysis were conducted separately for cases and controls below or above 45 years of age (data not shown). The odds ratios for number of childhood infections does not decrease with increasing number and does not substantially differ from the odds ratio from measles infection alone.

In Table 3 the risk of childhood diseases for two histological subtypes of NHL, in particular the negative associations found with measles exposure tended to be stronger for follicular B-cell NHL (OR 0.4, 95% CI: 0.2–0.8) than for diffuse large B-cell. Heterogeneity by histological subtype, however, did not demonstrate any statistical significance.

The inverse association between childhood diseases and risk of HL was restricted to nodular sclerosis HL (OR 0.3, 95% CI: 0.1–0.7). However, there were few cases of histological subtype other than nodular sclerosis (*n* = 19), limiting the power to detect any association with other HL subtypes (data not shown).

Table 2

Odds ratios (OR)^a and 95% confidence intervals (CI) for non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma (HL) according to childhood infections (Italy, 1999–2002)

	Controls		NHL		OR	(95% CI)	HL		OR	(95% CI)
	No.	(%)	No.	(%)			No.	(%)		
Viral infections										
Infectious mononucleosis										
Never	501	(99.4)	223	(99.1)	1 ^b		60	(96.8)	1 ^b	
Ever	3	(0.6)	2	(0.9)	1.5	(0.2–9.4)	2	(3.2)	1.9	(0.2–16.4)
Parotitis (mumps)										
Never	269	(53.4)	117	(52.0)	1 ^b		35	(56.5)	1 ^b	
Ever	235	(46.6)	108	(48.0)	0.9	(0.7–1.3)	27	(43.6)	0.5	(0.3–1.0)
Measles										
Never	163	(32.3)	84	(37.3)	1 ^b		25	(40.3)	1 ^b	
Ever	341	(67.7)	141	(62.7)	0.6	(0.5–0.9)	37	(59.7)	0.3	(0.2–0.7)
Rubella (German measles)										
Never	391	(77.6)	161	(71.6)	1 ^b		46	(74.2)	1 ^b	
Ever	113	(22.4)	64	(28.4)	1.1	(0.8–1.7)	16	(25.8)	0.5	(0.2–1.0)
Chickenpox										
Never	277	(55.0)	128	(56.9)	1 ^b		30	(48.4)	1 ^b	
Ever	227	(45.0)	97	(43.1)	0.9	(0.6–1.2)	32	(51.6)	0.5	(0.2–0.9)
Bacterial infections										
Pertussis (whooping-cough)										
Never	377	(74.8)	174	(77.3)	1 ^b		48	(77.4)	1 ^b	
Ever	127	(25.2)	51	(22.7)	0.7	(0.5–1.1)	14	(22.6)	0.5	(0.2–1.0)
Scarlet fever										
Never	455	(90.3)	198	(88.0)	1 ^b		60	(96.8)	1 ^b	
Ever	49	(9.7)	27	(12.0)	1.2	(0.7–2.0)	2	(3.2)	0.2	(0.0–1.0)
Number of childhood infections										
0	106	(21.0)	59	(26.2)	1 ^b		13	(21.0)	1 ^b	
1–2	210	(41.7)	76	(33.8)	0.5	(0.3–0.8)	21	(33.9)	0.2	(0.1–0.6)
≥3	188	(37.3)	90	(40.0)	0.6	(0.4–1.0)	28	(45.2)	0.2	(0.1–0.5)

^a Estimates from unconditional logistic regression equations, including terms for center, age, gender and years of education, and place of birth.

^b Reference category.

Table 3

Odds ratios (OR)^a and 95% confidence intervals (CI) for major non-Hodgkin lymphoma (NHL) subtypes in relation to history of childhood infections (Italy, 1999–2002)

Risk factors	Controls (No.)	Non-Hodgkin lymphomas								
		Follicular B-cell (36 cases)			Diffuse large B-cell (112 cases)			Other subtypes (77 cases)		
		No.	OR	(95% CI)	No.	OR	(95% CI)	No.	OR	(95% CI)
Viral infections										
Parotitis (mumps)										
Never	269	22	1 ^b		53	1 ^b		42	1 ^b	
Ever	235	14	0.6	(0.3–1.3)	59	1.1	(0.7–1.7)	35	0.8	(0.5–1.4)
Measles										
Never	163	17	1 ^b		39	1 ^b		28	1 ^b	
Ever	341	19	0.4	(0.2–0.8)	73	0.7	(0.5–1.2)	49	0.7	(0.4–1.1)
Rubella (German measles)										
Never	391	28	1 ^b		77	1 ^b		56	1 ^b	
Ever	113	8	0.8	(0.3–1.9)	35	1.3	(0.8–2.1)	21	1.2	(0.6–2.2)
Chickenpox										
Never	277	20	1 ^b		64	1 ^b		44	1 ^b	
Ever	227	16	0.9	(0.4–1.9)	48	0.8	(0.5–1.3)	33	0.9	(0.5–1.5)
Bacterial infections										
Pertussis (whooping-cough)										
Never	377	31	1 ^b		82	1 ^b		61	1 ^b	
Ever	127	5	0.4	(0.1–1.1)	30	0.8	(0.5–1.4)	16	0.7	(0.4–1.3)
Scarlet fever										
Never	455	35	1 ^b		96	1 ^b		67	1 ^b	
Ever	49	1	0.3	(0.0–2.1)	16	1.3	(0.7–2.4)	10	1.4	(0.6–3.0)

^a Estimates from unconditional logistic regression equations, including terms for center, age, gender, years of education, and place of birth.

^b Reference category.

4. Discussion

The etiological agents (viruses and bacteria) involved in the examined diseases are very different. Several studies have reported a positive association between mononucleosis and risk of HL, but so far present, the mechanisms through which other childhood infections in general may protect against HL and possibly NHL are unknown [1,2,20]. Early infection may promote the development of the immune system (particularly cell-mediated, Th1-type immunity), which may explain why young-adulthood infection with EBV increases the risk of HL, but earlier infection is inversely associated with the risk [1,4,5].

For NHL, some studies have shown a negative association provided by certain childhood viral infections (e.g. measles and chicken pox) and certain childhood bacterial infections (e.g. pertussis) [7,21]. Our study showed a protective effect only by measles; this result agrees with other studies which reported that attenuated measles virus (MV) has therapeutic potential as a replicating oncolysis virus in models of non-Hodgkin lymphoma [22,23]. Moreover, a recent study reported that in the presence of an intact immune system, therapy with repleting MV stimulates a strong neutrophil anti-tumor response, which can be cytokine-enhanced to improve oncolysis [24]. In addition, there is already a study from 1981, which reported a regression of Hodgkin's disease after measles [25], while a recent study reported

a negative association between lymphoma and measles [26].

For HL, our results agree with the hypothesis that certain childhood infections may provide a protective effect with subsequent immunostimulation on HL [20,27]. Indirect support for this hypothesis is further provided by studies which show that having 1–2, or even 3 or more siblings, a surrogate marker of earlier exposure to common childhood pathogens, is inversely related to HL risk [28].

No change in relative risk was seen for age at onset of childhood diseases among siblings either HL or NHL. Perhaps, this may be due to the difficulty in establishing a specific age-at-onset time-frame, as the age the children are introduced to school varies, profoundly affecting disease transmission.

Our findings are consistent with the oncogenesis (oncogenic mechanism) of different lymphomas: both HL and the most frequent NHL subtypes, i.e. follicular cell and diffuse large B-cell lymphomas, derive from antigen-exposed B-cells which undergo neoplastic transformation within the germinal centers (GC) of lymph nodes or secondary lymphoid organs [29]. In particular, the process of somatic hyper mutation of immunoglobulin variable region genes, while generating antibody diversity and increasing antigen affinity, creates a 'permissive' setting for lymphoma genesis-associated chromosomal translocations and mutations to occur. Such process is mediated by B-cells interaction with T-lymphocytes [29].

Thus, B-cell lymphoma genesis is strictly dependent on biologic features of both target B-lymphocytes and T-cell subsets controlling their physiologic development. While HL arises from preapoptotic ‘crippled’ B-cells, rescued by the transforming event within the GC, most B-NHL derive from cells undergone favorable (ongoing) mutations of immunoglobulin genes [29,30]. In addition, while bystander T-cells have been shown to favorably affect prognosis of B-NHL [31], several evidences indicate that surrounding T-cells may promote tumor cells survival in HL [30]. Therefore HL and NHL display consistent differences in terms of both transformation-targeted cells and tumor cells interplay with normal T-cell populations. Common childhood infections are associated with the development of both humoral and long-lasting cell-mediated immune responses, with virus-specific T-cells persisting more than 11 years after exposure in the case of measles [32]. Virus-specific B- and T-cells may then exert a divergent role in lymphoma genesis, by creating a non-permissive immune microenvironment for HL development from ‘crippled’ B-cell progenitors while turning less efficient in controlling the expansion of NHL B-cells undergone favorable immunoglobulin gene mutations.

Due to the limits of our study, notably the reliance on the self-reported history of childhood infections and infectious mononucleosis, our results should be viewed with caution. In particular, the specific association of only measles with NHL could be due entirely to chance, or it could be due to the lack of statistical power to detect associations with other childhood infections. No clear reason emerges to expect higher prevalence of childhood infections among controls. As specified in Ref. [13], controls were admitted to the hospital for trauma (27%), for non-traumatic orthopaedic diseases (23%), for acute surgical conditions (22%), for eye diseases (14%), and for a variety of other illnesses (14%). All these conditions are apparently weekly related to childhood infections occurred several decades before. A recall bias for cases and controls is also possible, but highly unlikely, as the possible association between childhood diseases and lymphoma risk was not of public domain, and all interviews were performed in a similar hospital setting. Unfortunately, in Italy there are few studies of prevalence for adults of all these childhood infections. Furthermore the prevalence of childhood infections among our hospitalized controls is overlapping to Italian prevalence [33].

5. Conclusions

Our findings provide additional support to the hypothesis that infections by most common childhood pathogens may protect against HL [4,34] or, at least, be correlated with some other early exposure, which may lower the risk of HL in adulthood. In addition, our study is one of the few study to provide evidence that measles may provide a protective effect against NHL [22,23,25,35], particularly follicular B-cell lymphomas, which is in line with studies reporting that patients

with low-grade B-cell NHL had more benefit from the induction of the tumor-specific anti-idiopathic immune response [36]. Our results are still in agreement with other studies and are consistent with the hypothesis of an immunogenic stimulation provided by some childhood diseases [20,26].

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Exhibit V

Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients or media.

Some excipients are added to a vaccine for a specific purpose. These include:

Preservatives, to prevent contamination. For example, thimerosal.

Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.

Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These include:

Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.

Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.

Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts.

If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

Vaccine	Contains
Adenovirus	human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, pladone C, anhydrous lactose, microcrystalline cellulose, polacrillin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion
DTaP (Infanrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

Vaccine	Contains
DTaP-HepB-IPV (Pediatrix)	Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, glutaraldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium
Hib (ActHIB)	sodium chloride, modified Mueller and Miller medium (the culture medium contains milk-derived raw materials [casein derivatives]), formaldehyde, sucrose
Hib (Hiberix)	saline, synthetic medium, formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep B (Hepelisav-B)	vitamins and mineral salts, yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, phosphate buffered saline, sodium phosphate, dibasic dodecahydrate, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
Human Papillomavirus (HPV) (Gardasil 9)	vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Trivalent & Quadrivalent	octoxynol-10 (TRITON X-100), α -tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and <i>Spodoptera frugiperda</i> cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts
Influenza (Flucelvax) Trivalent & Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and β -propiolactone
Influenza (Flulaval) Trivalent & Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials)
Influenza (Fluvirin)	ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose

Vaccine	Contains
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, sucrose
Influenza (Fluzone) Intradermal	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, sucrose
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
Meningococcal (MenACWY-Menactra)	Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride
Meningococcal (MenACWY-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium
Meningococcal (MenB – Bexsero)	aluminum hydroxide, <i>E. coli</i> , histidine, sucrose, deoxycholate, kanamycin
Meningococcal (MenB – Trumenba)	defined fermentation growth media, polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, neomycin, bovine serum albumin
Pneumococcal (PCV13 – Prevnar 13)	soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	Eagle MEM modified medium, calf bovine serum, M-199 without calf bovine serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propiolactone
Rabies (RabAvert)	chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells [<i>DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.</i>]
Rotavirus (Rotarix)	Vero cells, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan [<i>Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.</i>]
Smallpox (Vaccinia) (ACAM2000)	African Green Monkey kidney (Vero) cells, HEPES, 2% human serum albumin, 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP

Vaccine	Contains
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, sodium chloride, water
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains bovine extracts, ammonium sulfate
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, modified Mueller's growth medium
Tdap (Boostrix)	modified Latham medium derived from bovine casein, Fenton medium containing a bovine extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium, sodium chloride
Typhoid (Vivotif Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin
Varicella (Varivax) <i>Frozen</i>	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varicella (Varivax) <i>Refrigerator Stable</i>	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles) (Zostavax) <i>Frozen</i>	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum
Zoster (Shingles) (Zostavax) <i>Refrigerator Stable</i>	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Zoster (Shingles) (Shingrix)	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80

A table listing vaccine excipients and media *by excipient* can be found in:

Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs* – 2013 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.

Exhibit W

MRC-5 (ATCC® CCL-171™)

Organism: **Homo sapiens, human** / Cell Type: **fibroblast** / Tissue: **lung** / Disease: **Normal**

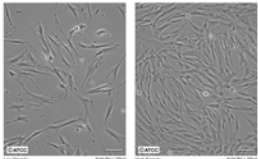
GENERAL INFORMATION	CHARACTERISTICS	CULTURE METHOD	SPECIFICATIONS	HISTORY	DOCUMENTATION	SHARE	EMAIL	PRINT
Karyotype	Chromosome Frequency Distribution 50 Cells: 2n = 46. This is a normal diploid human cell line with 46,XY karyotype. The modal chromosome number was 46, occurring in 70% of cells. The rate of polyploidy was 3.6%. Both X and Y chromosomes were normal. Note: Cytogenetic information is based on initial seed stock at ATCC. Cytogenetic instability has been reported in the literature for some cell lines.							
Images	<p>ATCC Number: CCL-171 Designation: MRC-5</p> 							
Derivation	The MRC-5 cell line was derived from normal lung tissue of a 14-week-old male fetus by J.P. Jacobs in September of 1966.							
Clinical Data	Caucasian male 14 weeks gestation							
Virus Susceptibility	Human poliovirus 1 Herpes simplex virus Vesicular stomatitis, Glasgow (Indiana) Vesicular stomatitis, Orsay (Indiana)							
Comments	The cells are capable of 42 to 46 population doublings before the onset of senescence.							

Exhibit X

WI-38 (ATCC® CCL-75™)

Organism: **Homo sapiens, human** / Cell Type: **fibroblast** / Tissue: **lung** / Disease: **normal**


GENERAL INFORMATION	CHARACTERISTICS	CULTURE METHOD	SPECIFICATIONS	HISTORY	DOCUMENTATION	SHARE	EMAIL	PRINT
Karyotype	normal diploid							
Images								
Derivation	The WI-38 human diploid cell line was derived by Leonard Hayflick from normal embryonic (3 months gestation) lung tissue.							
Clinical Data	3 months gestation fetus Caucasian female							
Virus Susceptibility	Vesicular stomatitis, Glasgow (Indiana) Herpes simplex virus Pseudorabies virus Human poliovirus 1							
Comments	<p>WI-38 cells have a finite lifetime of 50 plus or minus 10 population doublings with a doubling time of 24 hours. This line was the first human diploid cell line to be used in human vaccine preparation.</p> <p>The 8th passage ampule from which this freeze was derived was found to contain a bacterial contaminant (a micrococcus). The cell line was subsequently cured by several passages in the presence of antibiotics.</p> <p>Growth of the cells is enhanced by addition of tumor necrosis factor alpha (TNF alpha) to the medium.</p> <p>This cell line is negative for reverse transcriptase.</p>							

Exhibit Y

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Colloquy: Letters to the editor are invited on matters discussed in the *Quarterly* and on topics of general interest to Catholic bioethics.

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Case Studies: We seek case studies from physicians, nurses, health-care workers, lawyers, clergy, and others who have experience of particular cases that exemplify larger concerns in the field of bioethics. When necessary, names and identities should be altered to preserve confidentiality. Length may vary.

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A Brief History of Human Diploid Cell Strains

Rene Leiva, M.D.

The Pontifical Academy for Life published a response about the moral legitimacy of immunizing children with vaccines manufactured using cell strains derived from aborted human fetuses. In order to fully appreciate the level of cooperation involved among different agents, it is important to review the history of the development of these cell strains: “The need to articulate a moral reflection on the matter in question arises mainly from the connection which exists between the vaccines mentioned above and the procured abortions from which biological material necessary for their preparation was obtained.”¹

Human diploid cell strains (HDCSs) are batches of cells that are currently used for different purposes, including culturing viruses for the manufacturing of vaccines. HDCS-derived human vaccines have been licensed worldwide for polio IVP and OVP, rabies, rubella, measles, varicella-zoster, mumps, and hepatitis A. Current vaccines contain extremely small traces of the original fetal DNA, while the cell strains contain the complete fetal chromosomal set. The choice of HDCS was made among several based on their susceptibility to many human viruses, their good characterization, the enormous number of cells obtained from one original culture, their long

¹ Pontifical Academy for Life, “Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Fetuses” (June 5, 2005), <http://www.academiavita.org/template.jsp?sez=Documenti&pag=testo/vacc/vacc&lang=English>; reprinted in this issue of the *Quarterly* on pp. 541–549.

storage potential, the low cost of cell procurement, an excellent record of safety, and the very low risk of latent virus on the cells themselves.²

Even though there are many cell strains in use in research, the most well known are WI-38 and MRC-5. These two cell strains come from two deliberately aborted fetuses. But as the evidence shows, there were more abortions involved to achieve the technical expertise needed for development of these cell strains. In addition, other cell strains have been developed for vaccine manufacturing and other purposes. Because of its relevance to this discussion, I will also review the history of the virus strain RA 27/3, as it is the source of the only rubella vaccine available in North America and in fact, most of the world. Finally, as my intention is to capture the real meaning of the evidence, I will quote from the actual sources and personal communications to try to respect the original meaning.

Human Diploid Cell Strains

The Wistar Institute is a scientific institute located on the campus of the University of Pennsylvania in Philadelphia, specializing in the fields of immunology and cell biology. Working for the Institute in 1961, Dr. Leonard Hayflick first published a paper describing twenty-five HDCS: WI-1 through WI-25 (Wistar Institute fetal samples nos. 1–25). These cell strains were derived from the lung, skin, muscle, kidney, heart, thyroid, thymus and liver of nineteen separate, electively-aborted fetuses. The purpose of choosing different organs was to test difference in tissue characteristics. His research included also testing these cell strains' susceptibility for different viruses. He stated in this paper that

the isolation and characterization of HDCS from fetal tissue make this type of cell available as a substrate for the production of live virus vaccines. Other than the economical advantages, such strains ... make the consideration of their use in the production of human virus vaccine a distinct possibility.³

Abortion was illegal in the United States at that time, so fetal tissue was provided by Dr. Sven Gard of the Karolinska Institute Medical School in Stockholm, Sweden.⁴ Dr. Erling Norrby, who later served as chairman of the department of virology and dean of the medical faculty at the Karolinska Institute, was a graduate student there during this period. He dissected many of the aborted fetuses:

My predecessor as professor of virology at the Karolinska Institute in Stockholm, Sven Gard, spent a sabbatical year at the Wistar Institute in 1959,

²M. A. Fletcher, L. Hessel, and S. A. Plotkin, "Human Diploid Cell Strains (HDCS) Viral Vaccines," *Developments in Biological Standardization* 93 (1998): 97–107; L. Hayflick, "History of Cell Substrates Used for Human Biologicals," *Developments in Biological Standardization* 70 (1989): 11–26.

³L. Hayflick and P. S. Moorhead, "The Serial Cultivation of Human Diploid Cell Strains," *Experimental Cell Research* 25.3 (December 1961): 618.

⁴E. Norrby, "Listen to the Music: The Life of Hilary Koprowski (review)," *Perspectives in Biology and Medicine* 44.2 (Spring 2001): 304; Fletcher, Hessel, and Plotkin, "Human Diploid Cell Strains," 97–98.

two years after the institution had been taken over by the dynamic Koprowski. One of my duties as a young student in the laboratory in Stockholm was to dissect human fetuses from legal abortions and send organs to the Wistar Institute. Such material was the source of many important studies of cell lines at the Institute, such as Leonard Hayflick's study of WI-38 cells.⁵

Hayflick and his collaborators (including Anthony Girardi from the Merck Institute for Therapeutic Research) started working with these cell strains to develop viral vaccines: a poliovirus vaccine was developed in the WI-1 cell strain in 1962. By this time, fifty HDCSs had been made. Finally, after these improvements in the technique, Hayflick published his reports of the development of WI-38.⁶ WI-38 was obtained from a three-month-old female fetus:

This fetus was chosen by Dr. Sven Gard, specifically for this purpose. Both parents are known, and unfortunately for the story, they are married to each other, still alive and well, and living in Stockholm, presumably. The abortion was done because they felt they had too many children. There were no familial diseases in the history of either parent, and no history of cancer specifically in the families.⁷

This report also mentions two additional cell strains: WI-26 from a male fetus (lung) and WI-44 from a female fetus (lung). Both fetuses were about three-months' gestation as well.⁸

An article co-authored by Gard and colleagues at the Wistar Institute stated, in reference to Hayflick's cell strains, that

a human diploid cell strain derived from a fetal lung tissue was employed instead of monkey-kidney cells for the preparation of the attenuated poliovirus vaccine utilized in our study. The cell strain, cultivated especially for the production of virus vaccines, retains relatively constant morphology and chromosomal characteristics ... and it is believed to be free of all known adventitious agents. The expectation is that cells originating from a single fragment of tissue, passages of which are stored and cultivated at will, could be used in place of monkey cells ... to make large quantities of vaccine.⁹

On an interesting note, Hayflick was concerned about the continued capture of wild monkeys and their existence as species and saw HDCS as a solution to this

⁵ Norrby, "Listen to the Music," 304.

⁶ L. Hayflick, "The Limited In Vitro Lifetime of Human Diploid Cell Strains," *Experimental Cell Research* 37 (March 1965): 614-636; L. Hayflick et al., "Preparation of Poliovirus Vaccines in a Human Fetal Diploid Cell Strain," *American Journal of Hygiene* 75 (March 1962): 240-258.

⁷ "Gamma Globulin Prophylaxis; Inactivated Rubella Virus; Production and Biologics Control of Live Attenuated Rubella Virus Vaccines" [no author given], *American Journal of Diseases of Children* 118.2 (August 1969): 377-278.

⁸ Hayflick et al., "Preparation of Poliovirus Vaccines," 240, 244, 254.

⁹ J. S. Pagano et al., "The Response and the Lack of Spread in Swedish School Children Given an Attenuated Poliovirus Vaccine Prepared in a Human Diploid Cell Strain," *American Journal of Hygiene* 79 (January 1964): 74-75.

problem. A previous ethical version of these vaccines was developed from the kidney cells of the African green monkeys, an endangered species.¹⁰ Also, Hayflick himself became a vaccine developer for a polio vaccine and fought and won the legal right to hold a patent and profit from WI-38.¹¹ Finally, Hayflick was one of the co-signers of a letter sent to President Bush in 2001 to support the destruction of human embryos that occurs in embryonic stem cell research:

For the past thirty-five years many of the common human virus vaccines—such as measles, rubella, hepatitis A, rabies and poliovirus—have been produced in cells derived from a human fetus to the benefit of tens of millions of Americans. Thus precedent has been established for the use of fetal tissue that would otherwise be discarded.¹²

He is on the scientific advisory board of Advanced Cell Technology, the private company that claimed to have cloned the first human embryo in 2002.

Dr. J. P. Jacobs published the development of the cell strain MRC-5 (Medical Research Council strain no. 5) in 1970. He replicated Hayflick's work with the purpose of creating cells strains for the production of vaccines:

The stability and integrity of the human foetal cell strain WI-38 ... explain the value of such material for the isolation of viruses and in the development of vaccines. We have developed another strain of cells, also derived from fetal lung tissue, taken from a fourteen-week male fetus removed for psychiatric reasons from a twenty-seven-year-old woman with a genetically normal family history and no sign of neoplastic disease both at abortion and for at least three years afterwards.¹³

There is the possibility that there may have been previous abortions performed to create MRC-5. In fact, Jacobs reported creating a second cell strain, MRC-9, by the use of a different aborted fetus:

the cells were derived from the lungs of a female fetus in 1974, whose gestational age was about fifteen weeks. The fetus was of normal development and was delivered of a fourteen-year-old mother whose pregnancy was terminated by therapeutic abortion because she was unmarried. The medical history of the mother and her family indicated nothing abnormal according to information given by the gynecologist who performed the operation. The lungs were dissected from the fetus immediately following the abortion...¹⁴

¹⁰ L. Hayflick, "The Choice of the Cell Substrate for Human Virus Vaccine Production," *Laboratory Practice* 19.1 (January 1970): 59.

¹¹ L. Hayflick, "History of Cell Substrates Used for Human Biologicals," *Developments in Biological Standardization* 70 (1989): 15.

¹² K. J. Arrow et al., "Nobel Laureates' Letter to President Bush," *Washington Post*, February 22, 2001, A02.

¹³ J. P. Jacobs, C. M. Jones, and J. P. Baille, "Characteristics of a Human Diploid Cell Designated MRC-5," *Nature* 227.5254 (July 11, 1970): 168.

¹⁴ J. P. Jacobs, A. J. Garrett, and R. Merton, "Characteristics of a Serially Propagated Human Diploid Cell Designated MRC-9," *Journal of Biological Standardization* 7.2 (April 1979): 114.

Newer HDCSs continued to be made as back-ups for the current cell strains. Among the most common ones are IMR-90, cell strain 293, and PER C6.¹⁵ In short, IMR-90 was established from a sixteen-week-old human fetus on July 7, 1975, from a therapeutic abortion performed on a thirty-eight-year-old white mother of six.¹⁶ Cell strain 293 was made from human embryonic kidney cells from an aborted fetus in 1972, and cell strain PER C6 from human embryonic retina cells from an abortion in 1985. The main researcher was Dr. A. J. van der Eb at Leiden University in Holland. Van der Eb dissected the fetuses himself, which were healthy. PER C6 came from an eighteen-week-old aborted fetus because “the woman wanted to get rid of the fetus and the father was unknown.” Van der Eb stated that “PER C6 was made just for the pharmaceutical manufacturing of adenovirus vectors.” He also added, “I realize that this sounds a bit commercial, but PER C6 was made for that particular purpose.” Cell strain 293 was made for “basic research.”¹⁷ At least fifty companies have licensed PER C6, including Merck, the sole manufacturer of the only rubella vaccine available in North America.¹⁸

The Origin of Rubella Virus RA 27/3

Currently, the virus strain (RA 27/3) found in the rubella vaccine most commonly used around the world was developed by Dr. Stanley Plotkin and colleagues at the Wistar Institute.¹⁹ The RA 27/3 (rubella abortus, twenty-seventh fetus, third tissue extract) virus strain was obtained from a female human fetus in a series of twenty-seven abortions in the United States: “Explant cultures were made of the dissected organs of a particular fetus aborted because of rubella, the twenty-seventh in our series of fetuses aborted during the 1964 epidemic.”²⁰ “This fetus was from a twenty-five-year-old mother exposed to rubella eight weeks after her last menstrual period. . . . The fetus was surgically aborted seventeen days after maternal illness and dissected immediately. . . . It was then grown on WI-38.”²¹

¹⁵ W. W. Nichols et al., “Characterization of a New Human Diploid Cell Strain, IMR-90,” *Science* 196.4285 (April 1, 1977): 60; FDA Vaccines and Related Biological Products Advisory Committee, transcript of meeting May 16, 2001, “Session on Designer Cell Substrate,” http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3750t1_01.pdf.

¹⁶ Nichols et al., “Characterization of a New Human Diploid Cell Strain,” 60.

¹⁷ Alex J. van der Eb, in “Session on Designer Cell Substrates,” FDA meeting transcript, May 16, 2001.

¹⁸ L. Xie et al., “Large-Scale Propagation of a Replication-Defective Adenovirus Vector in Stirred-Tank Bioreactor PER.C6 Cell Culture under Sparging Conditions,” *Biotechnology and Bioengineering* 83.1 (July 5, 2003): 45.

¹⁹ S. A. Plotkin, D. Cornfeld, and T.H. Ingalls, “Studies of Immunization with Living Rubella Virus: Trials in Children with a Strain Cultured from an Aborted Fetus,” *American Journal of Diseases of Children* 110.4 (October 1965): 381–382.

²⁰ S. A. Plotkin et al., “Attenuation of RA 27-3 Rubella Virus in WI-38 Human Diploid Cells,” *American Journal of Disabilities of Children* 118.2 (August 1969): 178.

²¹ Plotkin, Cornfeld, and Ingalls, “Studies of Immunization with Living Rubella Virus,” 381–382.

The new vaccine was tested on children at a Roman Catholic orphanage in Philadelphia. It is documented that there were other effective virus strains already made at that time which had been obtained from other non-abortion-related methods.²² Nevertheless, the researchers seem to have chosen RA 27/3 because of its lack of contaminants, immunogenicity, low side effects, and enormous cell growth. Also, RA 27/3 was further cultured with the cell strain WI-38.

Additionally, six months after publishing this research, Plotkin and colleagues published an article documenting forty, not twenty-seven, abortions:

Out of the forty rubella fetuses cultured, cell strains were derived from thirty-four; in most cases they originated from pieces of skin and muscle obtained at curettage ... rubella virus was isolated from the supernatant culture medium of cell strains derived from eighteen fetuses; sixteen fetuses yielded cell strains which were rubella negative.²³

The RA 27 fetus was not the first fetus in the series to be positive for rubella virus. It is not clear why they continued with the series.

Later, Drs. J. Hoskins and Plotkin tested the action of the RA 27/3 virus on different systems of human embryonic cell cultures. Additional cell strains were made from more fetuses originating in both elective abortions (twenty-one) and miscarriages (seven):²⁴

Two groups of human fetuses, eight to twenty weeks, were used for the initiation of diploid cell strains. The first group consisted of normal embryos obtained by hysterotomy and flown from Scandinavia... The second group represented spontaneous abortions obtained from the gynecologic service of the Philadelphia General Hospital.²⁵

From the records, it also seems that both sources of cell strains yielded similar efficacy:

Cell strains derived from twenty-nine fetuses were examined. Twenty one of these originated from surgical abortions, while seven came from spontaneously aborted fetuses. One cell strain was of uncertain origin. At the start of these studies, most importance was attached to HDCS derived from the surgically aborted fetuses since these could be presumed to be normal. In fact, no differences in any of the parameters studied could be found between the two groups of fetuses, and no distinction will henceforth be made between them.²⁶

²² F. T. Perkins, "Licensed Vaccines," *Reviews of Infectious Diseases* 7 (March–April 1985), Suppl 1: S73–S76.

²³ T. H. Chang et al., "Chromosome Studies of Human Cells Infected in Utero and In Vitro with Rubella Virus," *Proceedings of the Society for Experimental Biology and Medicine* 122.1 (May 1966): 237–238.

²⁴ J. M. Hoskins and S. A. Plotkin, "Behaviour of Rubella Virus in Human Diploid Cell Strains. I. Growth of Virus," *Archiv fur die Gesamte Virusforschung* 21.3 (1967): 285; J. M. Hoskins and S. A. Plotkin, "Behaviour of Rubella Virus in Human Diploid Cell Strains. II. Studies of Infected Cells," *Archiv fur die Gesamte Virusforschung* 21.3 (1967): 297.

²⁵ Hoskins and Plotkin, "Behaviour of Rubella Virus I," 285.

²⁶ Hoskins and Plotkin, "Behaviour of Rubella Virus II," 297.

(Please note the arithmetic error, as twenty-one and seven do not add up to twenty-nine fetuses. It could have been one more aborted fetus or one extra miscarriage).

Plotkin later developed experimental polio, varicella, and cytomegalovirus vaccines. He is now employed at Sanofi Pasteur, a vaccine manufacturer. He believes that his rubella vaccine has helped to prevent many abortions: “I have no doubt that rubella vaccination has prevented thousands and thousands of abortions,” he said. “From strictly an arithmetical assessment, the good done by the vaccine—if you are opposed to abortion—is infinitely greater than any possible harm.”²⁷

The Manufacturers

At this point, it is important to mention that pharmaceutical companies in both Europe and North America quickly became involved in the use of HDCSs.²⁸ The World Health Organization in joint effort with the Wistar Institute funded meetings and training sessions with individuals interested in learning about HDCSs during the 1960s.²⁹

Given the fact that the research was public knowledge, it is impossible that the companies were unaware of the ethical predicament. To the researchers’ credit, they never hid the real source of the cells, as the titles of their articles confirm.³⁰ As stated in the written evidence, at least one collaborator in the research was working for a pharmaceutical company at the time the research was being done. Besides, the minimum requirements of safety standards dictate that a manufacturing pharmaceutical company know in detail the source of its raw material. The question has been posed whether this is like benefiting from the use of an organ from an executed persons or from unethical Nazi research.³¹

The Abortions

As I am also preparing an article for a Canadian medical journal on immunization, refusal, safety, and informed consent but not necessarily on the moral point of view, I needed to be able to assess the vaccines’ track of safety. In order to do this, it was necessary to trace back to the original abortions to ensure that there were no foreign dangerous contaminants. I thus emailed Dr. Norrby about this problem. Dr. Norrby stated that the cell strains were safe, since the tissue was collected in a very sterile manner:

When we collected the organs this was done immediately after the legal abortion. We were on duty to immediately perform the sampling and to arrange for

²⁷ D. Brown, “Rubella Virus Eliminated in the United States,” *Washington Post*, March 21, 2005, A07.

²⁸ Fletcher, Hessel, and Plotkin, “Human Diploid Cell Strains,” 97–98.

²⁹ Hayflick, “History of Cell Substrates,” 15.

³⁰ Plotkin, Cornfield, and Ingalls, “Studies of Immunization with Living Rubella Virus,” 381–382.

³¹ R. K. Zimmerman, “Ethical Analyses of Vaccines Grown in Human Cell Strains Derived from Abortion: Arguments and Internet Search,” *Vaccine* 22.31–32 (October 22, 2004): 4238–4244.

an as rapid transport as possible over the Atlantic Ocean. The fetal material arrived by car from the nearby hospital to our laboratory enwrapped in a green surgical cloth. Maximal sterility was critical to allow an outgrowth of fetal cells without any contamination after the transport under cold conditions to the Wistar Institute.³²

Whether there was any coercion in the abortions in order to procure these cell strains is unknown. We will also probably never know whether the mothers were actually aware that their abortions may have been used for the creation of cell strains, given what Dr. Norrby states regarding informed consent:

Remember that at the time in the early 1960s when organs from aborted fetuses were collected and sent to the Wistar Institute no one had as yet invented the concept of informed consent. I am absolutely convinced that there is no remaining documentation about the fetuses used from the Department of Virus Research of the Karolinska Institute at the time. I was the head of this department between 1972 and 1997. Thus in case there is no documentation that allows identification of fetal samples at the Wistar Institute, there is no way of tracing them. I do in fact remember the time well, because we as graduate students made the dissections collecting organs.³³

Conclusion

There is clear evidence that research around the development of the RA 27/3 rubella vaccine included the performance and coordination of at least eighty abortions, including the two individual abortions for the creation of WI-38 and RA 27/3. Development of MRC-5 used one abortion, but there is a strong indication that more abortions occurred. Evidence also seems to indicate that there was intention in the act of utilizing abortions for the creation of cell strains, most likely because the tissue source ensures an absence of contamination and a high growth titer. There have been other abortions as a result of the need to create more cell strains for use in vaccine development.³⁴ Pharmaceutical companies are actively involved in this research and

³² E. Norrby, e-mail response to a message from R. Leiva on January 23, 2006. Dr. Leiva had asked: “You mention that the step you were involved in (dissection of the fetal tissue) was done under sterile conditions. What about the steps of the procedure prior to that? Do you know anything about the conditions between the therapeutic abortions and the dissections? Were they both happening one after the other in the same facility and laboratory standards?”

³³ E. Norrby, e-mail response to a message from R. Leiva on January 20, 2006. Dr. Leiva had asked: “(1) Was the reason for the pregnancies’ termination medical or socio-therapeutic? (i.e., were diseases in the fetuses the reasons for the terminations?) (2) Was there good documentation regarding the health of parents of the fetuses? If so, where this can be obtained? (3) How were particular fetuses chosen? (Were there any medical reasons for choosing a particular fetus as Dr. Gard says in reference 2, or did the parents have any input in the choice. And (4) How was the termination–dissection–set-up organized to decrease the risk of introducing any kind of contaminants?”

³⁴ M. G. Pau et al., “The Human Cell Line PER.C6 Provides a New Manufacturing System for the Production of Influenza Vaccines,” *Vaccine* 19.17–19 (March 21, 2001): 2716–2721.

new vaccines are being made with unethical cell strains.³⁵ There are alternative ethical viral vaccines already made with modern cell substrates: Cell lines such as mammalian cells like Vero monkey cells and Chinese hamster ovary cells (e.g. some Polio IVP).³⁶ Alternatively, producing vaccines with antigens using recombinant DNA technology is another option (e.g.: hepatitis B).³⁷ Efforts should be made to encourage research on these and other novel ethical sources.

³⁵ M. N. Oxman et al. for the Shingles Prevention Study, “A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults,” *New England Journal of Medicine* 352.22 (June 2, 2005): 2271–2284.

³⁶ L. Hayflick, “History of Cell Substrates,” 24.

³⁷ D. B. Huang, J. J. Wu, and S. K. Tying, “A Review of Licensed Viral Vaccines, Some of their Safety Concerns, and the Advances in the Development of Investigational Viral Vaccines,” *Journal of Infection* 49.3 (October 2004): 179–209.

Exhibit Z

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Cytological Virological and Chromosomal Studies of Cell Strains From Aborted Human Fetuses.* (31037)

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Spontaneous abortion, usually without obvious cause, is a frequent occurrence in human pregnancies. To test the hypothesis that viral infections may play a part in the development of spontaneous abortion, a technique was sought to obtain dividing cells from human embryos that might be carrying latent viruses. We used a method developed by Jensen *et al*, for studying mouse tissues, in which cells could be obtained readily from organ explants. In the course of this work we collected cytological and chromosomal data on human fibroblast cell strains.

Materials and methods. Collection and preparation of specimens. Embryos were obtained from 2 sources: (A) surgical abortions performed in Scandinavia for social and psychiatric reasons, and (B) spontaneous abortions that occurred at the Philadelphia General Hospital and the Hospital of the University of Pennsylvania. The surgically removed embryos were placed in antibiotics containing Hanks' solution and shipped to us

by air at a temperature of approximately 0°C. The spontaneous abortions were refrigerated in plastic bags without solution or antibiotics until collected, usually within 12 hours. Only those embryos which were expected to have viable tissues were studied. Aside from the decomposed external appearance, one of the best indicators of the embryo's condition appeared to be the physical aspect of the liver. All assays performed on embryos with friable and discolored livers were discarded, because the cells failed to grow.

Organ culture technique. The organ culture technique described by Jensen *et al*(1) was used: a grid of stainless steel mesh|| was enclosed in a small Petri dish containing 10 ml of double strength Eagle's Basal Medium in isotonic Earle's solution with 10% calf serum; a small disc of open mesh paper (tea bag paper)** was moistened in the medium and applied to the top of the grid. Fragments of organs were cut into pieces about one cubic mm with a surgical blade and placed directly on the tea bag paper without being washed. Two explants were placed on top of each paper; the volume of the individual explants did not exceed 2 cu mm. The

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|| Joseph E. Frankle Co., Philadelphia, Pa.

** C. H. Dexter & Sons, Inc., Windsor Locks, Conn. (10-V-7-1/4).

cultures were incubated at 37°C in a CO₂ incubator and the medium changed once a week. Cells migrated from the cut surfaces of the explant and dropped to the bottom of the Petri dish, where they multiplied to form colonies and, in some cases, confluent cultures.

Establishment of cell strains. If the colonies became confluent and covered the entire surface of the Petri dish, a cell strain was established by trypsinizing the cells and subcultivating them, either in Petri dishes or in milk dilution bottles at a 1:2 split ratio.

During the first trypsinization, the grid was removed and placed in a second Petri dish and new colonies proliferated. After establishment of the cell strain, the technique used was the same as that of Hayflick(2) for cultivation of human diploid cell strains, whereby cultures were passaged approximately once a week with 2-fold subdivision.

Cytologic studies. Cytologic studies were conducted either on the colonies of cells that developed on the surface of the Petri dish or on established cell strains. Preparations stained with May-Grünwald-Giemsa were obtained by placing coverslips on the floor of the Petri dish under the grid bearing the organ culture or under passaged cells.

Chromosomal technique. This technique was derived from Lejeune(3). All the chromosomal studies were done on coverslips placed on the floor of the Petri dish under the grid or in Leighton tubes or on Petri dishes inoculated with resuspended cells after the cell strain had been established.

The cells were pretreated with colchicine by adding one drop of a stock solution of "Colcemide" (Ciba) containing 25 µg/ml to 5 ml of supernatant medium with a syringe and 24-gauge needle. The culture was incubated at 37°C for 3½ hours. The coverslip was transferred, face up, to a Petri dish that contained a hypotonic solution and was kept at 37°C for 35 minutes.

The hypotonic solution was a mixture of one part calf serum, 10 parts distilled water, and sufficient hyaluronidase ("Widase," Wyeth) to give 2.5 USP units per ml of the mixture.

The concentration of serum in the hypo-

tonic solution varied, depending on the density of the cells on the coverslip. When the density of the cells was high, the concentration of serum was lowered.

After hypotonic treatment, the coverslips were removed and put into a new Petri dish with the fixative and left for 45 minutes at room temperature.

The fixative consisted of 3 parts chloroform, one part acetic acid, and 6 parts absolute ethyl alcohol. The coverslips were then air dried and placed in a 1 N HCl solution at 60°C for 7 minutes so that the cytoplasm could be hydrolyzed. The coverslips were washed thoroughly in buffered water and stained with Giemsa solution diluted 1 to 10.

Results. These studies were performed from March to July, 1962, when 36 embryos were used, and again from November, 1963 to May, 1964, with 40 embryos.

Growth of cells from organ cultures. Each Petri dish was examined at least once a week with an inverted microscope. The time interval between the start of the organ culture and the formation of the first colonies of a few cells growing on the bottom of the Petri dish differed greatly from one embryo to another. In some cases, the colonies started at the end of the first week, while in other cases, they started only after 3 to 4 weeks of incubation. Most colonies grew well and after 3 weeks measured several millimeters in diameter.

The criterion of success of a culture was whether or not cell colonies developed after one month on the bottom of the Petri dish that contained the tissue-bearing grid. Cell growth from at least one tissue failed to occur only in 14 out of 76 aborted embryos: 8 from Scandinavia, 4 from PGH and 2 from HUP.

In the first series, the last 7 out of 26 embryos received from Scandinavia did not give viable cultures. The non-viability of cultures was probably due to the high external temperature during their shipment in July. Of the 12 received from HUP, 2 were lost by contamination and 2 failed to grow. Successful cultures, however, were obtained from 25 embryos (6 from the HUP and 19 from Finland).

Of the 40 aborted fetuses studied between

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TABLE I. Cell Growth Under Organ Cultures.

Organ	—Embryos studied from Nov. '63 to May '64—				Embryos studied Mar. to July '62		Total
	No. of embryos studied	Confluent cultures	Cell colonies	No growth	Successful*	Successful	
Pituitary	21	15	4	2	19/21	25/27	44/48
Lung	30	27		3	27/30	12/15	39/45
Skin	30	25		4	26/30	8/8	34/38
Kidney	14	10	4		14/14	6/7	20/22
Spleen	12	3	8	1	11/12	4/7	15/19
Thymus	15	11	2	2	13/15	2/2	15/17
Heart	8		1	7	1/8	1/5	2/13
Intestine	8	1	4	3	5/8	0/4	5/12
Liver	7		6	1	6/7	0/4	6/11
Thyroid	5	5			5/5	2/3	7/8
Salivary glands						5/5	5/5
Adrenals						2/5	2/5
Pharyngeal mucosa	2	2			2/2		2/2
Whole embryo	1	1				1/1	2/2
Cornea						1/1	1/1
Meningea						1/1	1/1
Tongue						1/1	1/1

* Denominator: No. of embryo studied; numerator: No. of cultures with successful growth.

November, 1963, and May, 1964, 13 were sent from Scandinavia, 20 came from PGH, and 7 from HUP. Successful cultures were obtained from 12, 16 and 7 embryos, respectively. Table I presents the results of organ cultures initiated with tissues from 60 embryos (31 from Scandinavia, 16 from PGH, and 13 from HUP). At least one organ culture from this group was successful.

There is a distinction between confluent culture and cell colonies: in the former case, the cultures came to confluence and could then be used to establish a cell strain, while in the latter case, only discrete colonies formed.

From these results it appears that, with the exception of heart organ cultures, most preparations resulted in cell growth on the glass. It was usually possible to obtain confluent cultures from such tissues as skin, lung, pituitary, kidney, thymus, thyroid, and pharyngeal mucosa.

The extremely low proportion of bacterial and fungal contaminations (2 of 76) in these organ cultures was noteworthy.

Establishment of cell strains. Table II summarizes the results of attempts to establish cell strains from the confluent cultures developed under the grids. While cell strains were easily established from skin, lung, pharyngeal mucosa and pituitary, it was difficult

to establish strains from intestine, thymus and thyroid.

All the cell strains were composed of fibroblast-like cells. With skin, lung and pharyngeal mucosa organ cultures, the cells under the grid were already predominantly fibroblastic; in the case of other organ cultures such as pituitary, thymus and thyroid the cultures at first appeared to be epithelial, but after the first trypsinizations became fibroblastic.

All of the cell strains had the previously described characteristics(2) for human diploid cell strains.

Virological studies. Two types of speci-

TABLE II. Establishment of Cell Strains.

Organ	No. of embryos studied	Culture successful for:		Culture unsuccessful at 1st split
		More than 4 splits 1:2	Fewer than 4 splits 1:2	
Skin	16	15	1	
Lung	12	10	2	
Kidney	5		4	1
Pituitary	5	3	1	1
Pharyngeal mucosa	4	4		
Intestine	4	1		3
Liver	3			3
Thymus	3	1	2	
Thyroid	3	1	2	
Whole embryo	1	1		

mens were tested in an attempt to isolate viruses from embryos. The test systems used in both types were primary vervet monkey kidney, primary human amnion, and human diploid cells (the WI-38 lung strain) (2).

In an attempt to detect latent viruses, the first type of specimen used was obtained from the cell cultures that became cell strains. No cytopathic effects were seen in any of the cells continuously cultured for periods ranging from one to six months. Tissue culture fluids obtained from cell strains cultured for 2 to 4 weeks were inoculated undiluted onto monolayers of the 3 tissue culture test systems. The test systems were maintained under Eagle's medium and 2% calf serum for 3 weeks before being discarded.

Suspension of cells derived from organ cultures were inoculated onto green monkey kidney cell monolayers, a technique described by Gerber and Kirschstein(4) for the transfer of cell-associated virus. All of these inoculations were negative.

The second type of specimen was the supernatant fluids from cultures which failed to grow. One might consider that the failure to establish a cell strain was due to a cytopathic effect. Tissue culture fluids were harvested over several weeks from organ cultures prepared from 5 embryos which yielded no cell growth from any culture. Inoculation of these fluids onto the test systems showed no evidence of cytopathogenicity.

When explants from a particular embryo gave both successful and unsuccessful cultures, the tissue culture fluids from unsuccessful explants were also tested for the presence of virus. Once more all attempts were negative. It is important to note that failure to grow cells from explants occurred in the same proportion in embryos from surgical abortions as in embryos obtained from spontaneous abortions.

We prepared organ cultures from 3 tonsils to test the sensitivity of the organ culture techniques for isolation of latent viruses when no cells grew from the explant. No cells grew in any of these cultures on the bottom of the Petri dish; however, in one case, 2 weeks after the beginning of the cultures, an adenovirus was recovered by passage on a sensitive

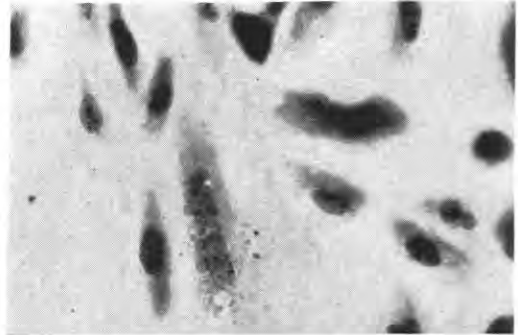


FIG. 1. Multinucleated giant cells seen in explant culture from a spontaneous abortion.

cell system of the medium harvested.

Cytological studies. Multinucleated cells were observed in many of the organ cultures, including explants from spontaneous and surgical abortions. Typical giant cells are illustrated in Fig. 1. Pituitary explants, in particular, gave rise to multinucleated cells, but when the cells were seen, their presence was noted in other cultures from the same embryo. Several days after the beginning of the culture, numerous giant-like cells containing 3 to 20 nuclei appeared. They were usually observed for the first time about the 12th day, but occasionally appeared before the seventh or as late as the 25th day of culture. The formation of multinucleated cells did not, in the majority of cases, prevent the eventual outgrowth of fibroblasts and development of a diploid strain. In pituitary cultures, the following sequence of events was observed: small colonies of epithelial-like cells appeared below the fragments, and later degenerated, giving way to a population of fibroblasts. As mentioned above, the fluids harvested from these cultures were tested on different cell systems with negative results. Some of the supernatant fluids were also inoculated into animals—such as baby mice by intraperitoneal and intracerebral routes, and baby hamsters by subcutaneous and intraperitoneal routes—without the isolation of a transmissible agent.

Chromosomal studies. Chromosomal study of cell cultures from 18 embryos of 2 to 4 months gestation was undertaken. Of these 18 embryos, all of which were obtained during the second time period of this work, 12

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were male and 6 female. Four out of the 18 were surgically aborted, and the rest were obtained from spontaneous abortions.

All of the cell strains were diploid with a normal karyotype of 46 chromosomes. In 2 cases, both spontaneous abortions, chromosomal breaks were observed. In a male embryo, 24 of 79 metaphases analyzed (30%), had true breaks or gaps of one chromatid or of the two chromatids. The distribution of these breaks was of a random type. In a female embryo, which was one of twins, breaks were observed in 11 of 49 metaphases or 22%. The other twin, a male, had a normal karyotype. In 5 cells these breaks were on chromosome 3, at the same region in one or both chromatids, while in 3 other cells a constriction was observed at the same region.

In the remainder of cell strains, the percentage of gaps was below 10%.

Discussion. In this study it has been demonstrated that it is possible to derive cell strains from organ explants of human tissues, using the simple method described by Jensen *et al.* This method could be useful when dealing with small amounts of tissue such as fetal organs. The strains derived seem to be similar in behavior to the human diploid fibroblast cell strains obtained from minced tissues by Hayflick and Moorhead.

It seems important to have techniques that permit the establishment of cell strains from different organs. Recent studies have shown that human diploid cell strains vary in their sensitivity to viruses. For example, we have shown(5) that the effects of rubella virus infection are related to the organ from which these cell strains were initiated. Recently Behbehani *et al*(6) found that cell strains derived from human atheromatous lesions seem to be particularly susceptible to rhinoviruses.

The failure to isolate viruses from the spontaneously aborted fetuses must of course be qualified by the fact that only cytopathogenic agents would have been detected. However, insofar as the results are negative, some support should be given to the view that human diploid cell strains are normally free of extraneous viruses, and they are, therefore, ad-

vantageous for the fabrication of vaccines and for studies on chronic viral infection in human cells.

The negative results do not entirely exclude the possibility that viral infection plays a role in spontaneous abortion because the abortion might be due to a secondary effect of viral infection of the mother that has occurred without passage of the virus to the embryo itself.

No abnormality of the karyotype was observed among the 18 embryos studied. The only aberration found was due to breakages in 30% and 22% of cells of two of them. These results were in accordance with the results of Makino *et al*(7), who found only 2 aberrations out of 135 embryos obtained from therapeutic abortions: one aberration was D Trisomic, and in the other, the cells were found to contain a high incidence of chromosome breakage.

Chromosomal aberrations were found in spontaneous abortions by Carr(8), Clendenin (9), Szulmann(10), Hall(11) and Thiede (12), but in each case, where chromosomal abnormalities were described, the specimen was pathologic and consisted of a degenerating embryo or of an empty sac without a trace of fetal tissue—the so-called blighted ovum. Moreover, these pathologic specimens led to abortion which occurred early in pregnancy, or before the third month. In our study, most of the specimens were obtained from abortions that occurred in the third month or later, and which produced normally developed embryos.

Summary. An organ culture technique was used to investigate the possibility that latent viruses are present in spontaneously aborted human fetuses. All attempts to isolate virus from 74 human embryos were negative. In the course of these studies, numerous cell strains were derived from human tissue, and cytological features of these cells are described. Multinucleated giant cells were frequently found, but chromosomal aberration in this material was infrequent.

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Received January 24, 1966. P.S.E.B.M., 1966, v122.

Activation of Factors XII (Hageman) and XI (PTA) by Skin Contact.* (31038)

H. L. NOSSEL (Introduced by L. R. Wasserman)

Department of Hematology, Mount Sinai Hospital, New York City

Blood coagulation can be initiated *in vitro* by contact with a foreign surface such as glass which activates Factors XII (Hageman) and XI (PTA)(1). Most known activating surfaces do not occur in the body and it is unknown whether similar reactions initiate *in vivo* coagulation. Recently stearic acid(2-6), uric acid(7) collagen and elastin(8) which are found *in vivo* have been shown to activate the Hageman and PTA factors. Evidence is presented below that blood contact with unbroken human skin results in accelerated clotting due to activation of the Hageman and PTA factors.

Materials and methods. Platelet-poor plasma was prepared without contact with glass or similar surfaces as previously described(6). Plasma deficient in Factors VIII, IX, XI or XII was obtained from patients with congenital deficiency of these factors. Celite exhausted plasma deficient only in Factors XII and XI was prepared by treating normal plasma with 20 mg celite per ml as previously described(6). Cephalin prepared as previously described(9) was used in a 1/100 dilution.

Coagulation was carried out in 10 × 75 mm glass tubes coated with siliclad (Clay-Adams). 0.1 volumes of plasma and cephalin were added to a silicone treated tube. The tube was inverted over an area of skin which

had been carefully cleaned with ether, alcohol and then distilled water and the plasma-cephalin mixture was incubated in contact with the cutaneous surface for a variable time period. The tube was turned upright, 0.1 ml 0.025 M CaCl₂ was added and the tube re-inverted over the same cutaneous site so that the clotting mixture was again in contact with the skin surface. The time required to form a solid clot was measured from the time calcium was added. In the control experiments exactly the same procedure was carried out except that parafilm (Marathon, Wisconsin) was interposed between the clotting mixture and the skin surface during both the incubation and clotting periods. Each clotting time was recorded as the average of those obtained in 3 tubes.

Results. Incubation of normal plasma in contact with a cutaneous surface resulted in progressive shortening of the clotting time (Fig. 1). Most of the acceleration of clotting occurred during the first minute of incubation and after 5 minutes incubation an almost maximal effect was noted. Skin surfaces in various sites exerted different degrees of clot promoting activity—the palmar surface of the hands and the skin of the face were particularly active. Prior cleansing of the skin with distilled water, ether or alcohol did not appear to affect the clot-promoting activity. When plasma samples from patients with congeni-

* This study was supported in part by Grant HE-08631 from Nat. Inst. Health, USPHS.

Exhibit AA



OPEN LETTER TO LEGISLATORS REGARDING FETAL CELL DNA IN VACCINES

April 8, 2019

My name is Dr. Theresa Deisher. I am Founder and Lead Scientist at Sound Choice Pharmaceutical Institute, whose mission is to educate the public about vaccine safety, as well as to pressure manufacturers to provide better and safer vaccines for the public. I obtained my doctorate from Stanford University in Molecular and Cellular Physiology in 1990 and completed my post-doctoral work at the University of Washington. My career has been spent in the commercial biotechnology industry, and I have done work from basic biological and drug discovery through clinical development.

I am writing regarding unrefuted scientific facts about fetal DNA contaminants in the Measles-Mumps-Rubella vaccine, which must be made known to lawmakers and the public.

Merck's MMR II vaccine (as well as the chickenpox, Pentacel, and all Hep-A containing vaccines) is manufactured using human fetal cell lines and is heavily contaminated with human fetal DNA from the production process. Levels in our children can reach up to 5 ng/ml after vaccination, depending on the age, weight and blood volume of the child. That level is known to activate Toll-like receptor 9 (TLR9), which can cause autoimmune attacks.

To illustrate the autoimmune capability of very small amounts of fetal DNA, consider this: labor is triggered by fetal DNA from the baby that builds up in the mother's bloodstream, triggering a massive immune rejection of the baby. This is labor.

It works like this: fetal DNA fragmentsⁱ from a baby with about 300 base pairs in length are found in a pregnant mother's serum. When they reach between 0.46– 5.08 ng/mL in serum, they trigger labor via the TLR9 mechanismⁱⁱ. The corresponding blood levels are 0.22 ng/ml and 3.12 ng/ml. The fetal DNA levels in a child after being injected with fetal-manufactured vaccines reach the same level that triggers autoimmune rejection of baby by mother.

Anyone who says that the fetal DNA contaminating our vaccines is harmless either does not know anything about immunity and Toll- like receptors or they are not telling the truth.

If fetal DNA can trigger labor (a naturally desired autoimmune reaction), then those same levels in vaccines can trigger autoimmunity in a child. Fragmented fetal DNA contained in vaccines is of similar size, ~215 base pairs.ⁱⁱⁱ

This is direct biological evidence that fetal DNA contaminants in vaccines are not in low innocuous amounts. They are a very strong proinflammatory trigger.



Administration of fragments of human fetal (primitive) non-self DNA to a child could generate an immune response that would also cross-react with the child's own DNA, since the contaminating DNA could have sections of overlap very similar to the child's own DNA.

Children with autistic disorder have antibodies against human DNA in their circulation that non-autistic children do not have. These antibodies may be involved in autoimmune attacks in autistic children.^{iv}

Duke University demonstrated in a recently conducted study that significant improvements in behavior were observed when children with autism spectrum disorder were treated with their own banked autologous cord blood^v. This treatment clearly shows that most children with autism are not born with it since genetic diseases like Down syndrome or muscular fibrosis cannot be treated with autologous stem cells. Therefore, an environmental trigger, or triggers, introduced to the world around 1980 when autism first began to rise, must be identified and eliminated or reduced in the environment.

- Strong change-point correlation exists between rising autism rates and the US vaccine manufacturing switch from animal-derived cell lines for rubella vaccine to human aborted cell lines in the late 70s^{vi}.
- The earliest change point for Autistic Disorder (AD) birth year was identified for 1981 for California and U.S. data, preceded by a switch in the manufacturing process:
 - In January 1979, the FDA approved the manufacturing switch for the rubella virus from animal based (high passage virus, HPV-77, grown e.g. in duck embryo cells) to the human fetal cell line WI-38 using the RA27/3 virus strain^{vii}. Both the newly approved monovalent rubella vaccine and a trivalent mumps, measles and rubella vaccine utilize the WI-38 fetal cell line for manufacturing of the rubella vaccine portion.
- Prior to 1980, autism spectrum disorder was a very rare, almost unknown disease. According to the figures of the CDC, the rate of autism in 2014 was 1 in 59 children, a very steep increase since just 2000, when it was 1 in 150. CDC: "The total costs per year for children with ASD in the United States were estimated to be between \$11.5 billion – \$60.9 billion (2011 US dollars)^{viii}."
- Recently, duplications and de novo deletions have been recognized in up to 10% of simplex autism spectrum disorders, corroborating environmental triggers on the genetics of autism spectrum disorders^{ix}.
- The rubella portion of the MMR vaccine contains human derived fetal DNA contaminants of about 175 ngs, more than 10x over the recommended WHO threshold of 10 ng per vaccine dose^x.
- No other drug on the market would receive FDA approval without thorough toxicity profiling (FDA follows international ICH guidelines) -> this was never conducted by the pharmaceutical industry for the DNA contamination in the MMR vaccine.
- Vaccines produced with human fetal cell lines contain cell debris and contaminating residual human DNA, which cannot be fully eliminated during the downstream purification process of the virus^{xi}. Moreover, DNA is not only characterized by its sequence (ATCG), but also by its epigenetic modification (e.g. DNA methylation pattern etc.). This decoration is highly species specific, which is why non-human DNA will be eliminated, while this is not necessarily the case with fetal human DNA.



Injecting our children with human fetal DNA contaminants bears the risk of causing two well-established pathologies:

- 1) Insertional mutagenesis: fetal human DNA incorporates into the child's DNA causing mutations. Gene therapy using small fragment homologous recombination has demonstrated that as low as 1.9 ng/ml of DNA fragments results in insertion into the genome of stem cells in 100% of mice injected^{xii}. The levels of human fetal DNA fragments in our children after vaccination with MMR, Varivax (chickenpox) or Hepatitis A containing vaccines reach levels beyond 1.9 ng/ml.
- 2) Autoimmune disease: fetal human DNA triggers a child's immune system to attack his/her own body.

An additional concern: retrovirus contamination.

Human endogenous retrovirus K (HERVK) is a contaminant in the measles/mumps/rubella vaccine^{xiii}.

- HERVK can be reactivated in humans^{xiv}. It codes for a protein (integrase) specialized in integrating DNA into the human genome.
- Several autoimmune diseases have been associated with HERVK activity^{xv}.
- It is also in the same family of retroviruses as the MMLV virus used in a gene therapy trial, in which inappropriate gene insertion (insertional mutagenesis) led to subsequent additional somatic mutations and cancer in 4 of 9 young boys^{xvi}.
- It is therefore possible that the HERVK gene fragment present in the MMR vaccine is active, codes for the integrase or the envelope protein, and thus has the potential to induce gene insertion, fostering insertional mutagenesis and autoimmunity.

The presence of both the high level contaminating fetal DNA as well as the HERVK contamination in the MMR vaccine is an unstudied risk with huge implications and dangers for individual and public health.

Solution: Pressure manufacturers to switch back to animal cell line derived rubella vaccines as was successfully done in Japan:

- Based on Takahashi strains of live attenuated rubella virus, produced on rabbit kidney cells. A single dose of this vaccine has been recently proven to retain immunity for at least 10 years when rubella was under regional control^{xvii}.
- Split MMR vaccine into three individually offered options as done in Japan.

The MMR vaccine manufacturing process needs to be changed to address and eliminate the above risks for the public.

Thank you for your consideration. I will be happy to address any questions you may have concerning the above.

Sincerely,

Theresa A. Deisher, Ph.D.



END NOTES

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Exhibit BB

Hearing Exhibit 3



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BETHESDA, MARYLAND 20914

page #1
SEP 15 1978

Our Reference Nos. 76-316, 77-303 and 77-304

Alan Gray, Ph.D.
Merck Sharp & Dohme
Division of Merck and Co., Inc.
West Point, Pennsylvania 19486

Dear Dr. Gray:


This is to inform you that the amendments to your product license applications to include the use of the RA27/3 strain rubella virus grown in human diploid cells have been accepted for manufacture of the following products:

Rubella Virus Vaccine, Live
Measles, Mumps and Rubella Virus Vaccine, Live
Measles and Rubella Virus Vaccine, Live

We agree that the results of stability testing of vaccines prepared with the buffered sorbitol-gelatin diluent support your request for a longer dating period. Accordingly, your license applications for the three products are also amended to include the use of the diluent and a dating period of two years at 2^o-8^o C from date of issue.

Please continue to submit stability data as they become available.

Sincerely yours,

for 
Harry M. Meyer, Jr., M.D.
Director
Bureau of Biologics

Summary No. 1
of
Clinical Investigative Studies
of

Combined Live Measles Virus Vaccine (Moraten Line-ATTENUVAX)
Jeryl Lynn Mumps Virus Vaccine (MUMPSVAX)
RA 27/3 Rubella Virus Vaccine

for Purpose of Support for
a License to Manufacture and Sell.



M. R. Hilleman, Ph.D.

Prepared: April 27, 1978
Merck Institute for Therapeutic Research
West Point, Pennsylvania

Clinical Investigative Studies of Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

1. Background

On January 11, 1978, we submitted "Summary No. 2 of Clinical Investigative Studies of RA 27/3 Strain Live Rubella Virus Vaccine for Support for a License to Manufacture and Sell" to the Bureau. That summary showed the RA 27/3 rubella virus vaccine to be safe and highly effective in inducing rubella hemagglutination-inhibition (HI) antibodies in persons of various ages.

In extension of clinical tests with RA 27/3 strain rubella virus vaccine, studies were conducted to evaluate its immunizing capability when combined with live attenuated Moraten line measles virus vaccine (ATTENUVAX) and Jeryl Lynn mumps virus vaccine (MUMPSVAX). The present submission relates to clinical investigative studies of combined live measles-mumps-rubella (RA 27/3) virus vaccine.

All clinical studies were conducted under BB-IND-1016.

2. Lot Numbers of Vaccine Tested

Experimental lot prepared by Virus and Cell Biology Research, Merck Sharp and Dohme Research Laboratories:

621/C-D763

Consistency lots prepared by Merck Sharp and Dohme Biologics Manufacturing:

60664/C-E810

60665/C-E811

60666/C-E812

3. Serologic Testing

Serologic determinations were made in the laboratories of Virus and Cell Biology Research, Merck Institute, and in the Control Laboratories of the Merck Sharp and Dohme Division of Merck & Co.

The hemagglutination-inhibition (HI) test was used to determine both measles antibody response and rubella antibody response. Starting dilutions in these two tests were 1:5 and 1:8, respectively. The serum neutralization test was used to measure mumps antibody response with a starting dilution of 1:2.

4. Clinical Studies

The clinical studies were conducted under the overall responsibility of Dr. Maurice R. Hilleman, Vice President, Virus and Cell Biology Research, Merck Institute for Therapeutic Research, West Point, Pennsylvania.

The clinical tests were carried out by five groups of workers:

- a. Dr. Robert E. Weibel, Director, Division of Preventive Medicine, Joseph Stokes, Jr. Research Institute, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
- b. Dr. Victor M. Villarejos, Director, Louisiana State University - International Center for Medical Research and Training, San Jose, Costa Rica
- c. Dr. Stephen J. Lerman, Director, Pediatric Infectious Disease Unit, Department of Pediatrics, The University of Nebraska Medical Center, Omaha, Nebraska
- d. Dr. Anne A. Gershon, Associate Professor, Department of Pediatrics, New York University Medical Center, New York, New York
- e. Dr. Robert W. McCollum and Dr. Dorothy M. Horstmann, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, Connecticut

Clinical studies fall into two main categories:

	<u>Reference</u>
a. Comparison of M-M-R (RA 27/3) and M-M-R (HPV-77) vaccines in children	3, 4, 5, 6
b. Serologic and clinical responses to measles-mumps-rubella (RA 27/3) vaccine	1, 2, 7, 8

The clinical studies were carried out by the physicians at the locations in the individual study summaries to follow. The populations employed were defined with respect to age, location and other pertinent parameters necessary to permit analysis by statistical sampling procedures.

Subjects in the sampled groups were bled initially and again 6 to 8 weeks later. The sera were tested to define the initial serostatus and the subsequent antibody response.

Clinical surveillance was by two procedures. In studies by Drs. Weibel, Lerman, Garshon, and McCollum, the observations were recorded daily by the mother. The parent was asked to contact the physician should any significant or bothersome reaction occur. In the studies by Dr. Villarejos, observations were made on a routine basis by medical or paramedical personnel; physicians were notified of any significant illness which occurred subsequent to vaccination.

The data presented in the following sections are self explanatory. The detailed background records are on file in Virus and Cell Biology Research, Merck Institute for Therapeutic Research, West Point, Pennsylvania. These records are available for review at any time.

5. Clinical Study Summaries

Reference 1 - Study 442 - Dr. Victor Villarejos

Details of the study plan are given in the clinical test protocol. The study was designed to measure antibody and clinical responses to the RA 27/3 rubella component when given alone or combined with mumps and/or measles vaccine. Findings presented in the summary tables indicate excellent antibody response to all components among children receiving live measles-mumps-rubella (RA 27/3) virus vaccine. No untoward clinical reactions were noted following vaccination.

Reference 2 - Study 443 - Dr. Robert Weibel

Details of the study plan are presented in the clinical protocol. The purpose of the study was to measure antibody and clinical responses to the RA 27/3 rubella component when given alone or combined with measles and mumps virus components. Findings are presented in the summary tables. Each of the three viruses produced excellent antibody responses when administered in combined form. Both vaccines were well tolerated.

Reference 3 - Study 459 - Dr. Stephen Lerman

Study 459 is being conducted in children to compare responses to HPV-77 and RA 27/3 rubella vaccines when given alone or combined with measles and mumps vaccines. Details of the study plan are given in the clinical test protocol. Preliminary findings presented in the summary tables show excellent antibody response to measles, mumps, and rubella components and lack of suppression when the three viruses are combined. Reaction rates were as expected.

Reference 4 - Study 467 - Dr. Robert Weibel

Study 467 was conducted among children to compare responses to combined measles-mumps-rubella vaccines containing either the HPV-77 or RA 27/3 rubella component. Details of the study plan are given in the clinical test protocol, and study results are presented in the summary tables. Antibody responses to both vaccines were excellent, indicating no reduced affect on any component in combined form. Reaction rates were as expected for both vaccines.

Reference 5 - Study 473 - Dr. Robert McCollum

Study 473 is being conducted among children to compare responses to combined measles-mumps-rubella virus vaccines containing either the HPV-77 or RA 27/3 rubella component. Details of the study plan are given in the clinical test protocol. No results are available at this time.

Reference 6 - Study 484 - Dr. Anne Gershon

Study 484 is being conducted among children to compare responses to combined measles-mumps-rubella virus vaccines containing either the HPV-77 or RA 27/3 rubella component. Preliminary findings are presented in the report from Dr. Gershon. The study continues in progress.

Reference 7 - Study 511 - Dr. Victor Villarejos

Study 511 was conducted to measure antibody and clinical responses to three consecutive lots of combined measles-mumps-rubella vaccine containing the RA 27/3 rubella component. Details of the study plan are given in the clinical test protocol, and study results are presented in the summary tables. Responses to the rubella component were excellent. Seroconversion rates for measles and mumps were somewhat lower than expected, and the decreased seroconversion rates were attributed to some overheating of the vaccine during transport in the field. Reaction rates were comparable among the lots.

Reference 8 - Study 513 - Dr. Robert Weibel

Study 513 is being conducted to measure antibody and clinical responses to three consecutive lots of combined measles-mumps-rubella vaccine containing the RA 27/3 rubella component. Study details are given in the clinical protocol, and preliminary findings are given in the summary tables. To date, all three lots of vaccine have produced good antibody responses and have been well tolerated.

6. Overall Summary

The total numbers of vaccinations for which supporting data have been given are as follows:

Lot #	No. Vacc.	<u>No. Seroconverting/No. Triple Negatives (%)</u>		
		<u>Measles</u>	<u>Mumps</u>	<u>RA 27/3 Rubella</u>
621	480	143/150 (95)	145/150 (97)	150/150 (100)
60664	144	50/55 (91)	52/55 (95)	55/55 (100)
60665	104	37/39 (95)	37/39 (95)	38/39 (97)
60666	106	34/35 (97)	34/35 (97)	34/35 (97)
Total	834	264/279 (95)	268/279 (96)	277/279 (99)

The data show that combined live measles-mumps-rubella vaccine containing the RA 27/3 rubella virus component is safe and effective.

Summary of Clinical Tests of Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Study No.	Investigator	Lot No.	Age		No. Vacc.	Antibody Responses among Triple Seronegatives									Re.
			Range	Mean (Yrs.)		Measles			Mumps			RA 27/3 Rubella			
						No. Conv./ No. Seroneg. (%)	GMT	No. Conv./ No. Seroneg. (%)	GMT	No. Conv./ No. Seroneg. (%)	GMT				
442	Villarejos	621	10m- 7y	3.7	199	23/23 (100)	99	22/23 (96)	7	23/23 (100)	149	1			
443	Weibel	621	11m- 8y	1.7	105	65/69 (94)	56	66/69 (96)	8	69/69 (100)	133	2			
459	Lerman	60664	14m- 4y	1.6	41	13/14 (93)	62	13/14 (93)	17	14/14 (100)	269	3			
467	Weibel	621	11m- 7y	1.9	137	55/58 (95)	71	57/58 (98)	7	58/58 (100)	146	4			
473	McCollum	621										5			
484	Gershon	621	13m-15y		39							6			
511	Villarejos	60664	8m-11y	3.3	50	9/11 (82)	20	10/11 (91)	5	11/11 (100)	226	7			
		60665	11m- 7y	3.3	50	4/5 (80)	25	4/5 (80)	11	5/5 (100)	169				
		60666	11m-11y	4.2	50	2/2 (100)	28	2/2 (100)	8	2/2 (100)	256				
513	Weibel	60664	12m- 7y	1.7	53	28/30 (93)	70	29/30 (97)	19	30/30 (100)	256	8			
		60665	12m- 4y	1.5	54	33/34 (97)	70	33/34 (97)	23	33/34 (97)	200				
		60666	11m- 4y	1.4	56	32/33 (97)	66	32/33 (97)	26	32/33 (97)	251				
		Totals			834	264/279 (95)	63	268/279 (96)	11	277/279 (99)	178				

Reference No. 1

Program: Study #442

Vaccine: Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine
Lot No. 621/C-D763

Combined Live Measles-Rubella (RA 27/3) Virus Vaccine
Lot No. 622/C-D764

Live Attenuated Rubella (RA 27/3) Virus Vaccine
Lot No. 579/C-D418

Responsible Clinical Investigator:

Victor M. Villarejos, M.D.
Director
Louisiana State University
International Center for Medical
Research and Training
Apartado 10.155
San Jose, Costa Rica

Study Location: Rivas, Nicaragua

Date Study Initiated: January 19, 1976

Date Study Completed: April 28, 1976

Study Procedure:

A total of 589 children, 10 months to 7 years of age, from the open population were included in the study. Each participant received a 0.5 ml subcutaneous dose of one of the three vaccines. Blood samples were obtained prior to and six weeks after vaccination.

Clinical Protocol - Study #442

Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine
Live Attenuated Rubella (RA 27/3) Virus Vaccine

Purpose: To determine antibody and clinical responses to combined live measles-mumps-rubella (RA 27/3) virus vaccine, to combined live measles-rubella (RA 27/3) virus vaccine, and to live attenuated rubella (RA 27/3) virus vaccine.

Vaccines: a) Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot No. 621

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

b) Combined live measles-rubella (RA 27/3) virus vaccine
Lot No. 622

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

c) Live attenuated rubella (RA 27/3) virus vaccine
Lot No. 579

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial of vaccine should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: The combined vaccines contain egg protein and should not be given to persons with known sensitivity to egg, chicken, or chicken feathers. All three vaccines contain neomycin and should not be given to persons with sensitivity to neomycin. Persons with leukemia or other immunologic disorders and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C until used.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccines on ice. Discard unused vaccine 4 hours after rehydration.

Clinical Protocol -
Study #442

-2-

Procedure: The study population will consist of children 1 to 6 years of age.

Children receiving a given vaccine will have a negative history for vaccination with and illness caused by viruses represented in that vaccine. Children will be assigned to receive one of the three vaccines as follows:

<u>Vaccine</u>	<u>Vaccine Lot</u>	<u>No. Children</u>
measles-mumps-rubella	621	150-200
measles-rubella	622	150-200
rubella	579	150-200

Informed consent will be obtained from each child's parent or guardian prior to his participation in the study.

Each child will be bled (10-15 ml) immediately prior to vaccination and 6 weeks following vaccination.

Vaccine dose is 0.5 ml given subcutaneously.

Each child will be followed clinically for 42 days following vaccination. All local and systemic complaints will be recorded on the case report form.

Schedule:

<u>Time</u>	<u>Action</u>
Day 0	Bleed 10-15 ml. Vaccinate 0.5 ml, subcutaneously.
Days 0-42	Clinical follow-up for local and systemic reactions.
Week 6	Bleed 10-15 ml.

Laboratory: Remove sera from clot aseptically and store frozen at -20°C until shipped. It is imperative that sera are sterile to avoid interference with the serologic assay.

Serology: Circulating levels of antibody to each vaccine component will be determined for samples drawn before and after vaccination. Measles and rubella antibody levels will be determined by hemagglutination-inhibition test. Mumps antibody levels will be determined by serum neutralization test.

Clinical
Forms: Attached.

Clinical Protocol -
Study #442

-3-

- Adverse Reactions: Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.
- Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pa. 19486.
- Shipping of Sera & Records:
- a) Send sera frozen within insulated containers which are supplied.
 - b) Send sera and records to Dr. Maurice R. Hilleman, Virus and Cell Biology Research, Merck Sharp & Dohme Research Laboratories, West Point, Pa. 19486.
 - c) Alert Dr. Hilleman by cable as soon as possible as to flight number, air bill, and date of arrival.


M. R. Hilleman, Ph.D.

VACUNACIÓN CONTRA SARAMPIÓN PAPELINAS RUBÉOLA

HOJA CLINICA

NO. DE CASO _____

B

FECHA DE VACUNACION _____
 día mes año

NOMBRE: _____

DIA	FECHA	Temperatura	Malestar	Anorexia	Gastroenteritis	Irritabilidad	Cefalea	I. V. R. S.	Otitis	Conjuntivitis	Linfadenopatía*	Reacción Local* (Diámetro mm)	RASH*			Artralgia*	Artritis*	*Especifique tipo en esta sección
													Exantema*	Rubelliforme	Morbilliforme			
		24	16	25	08	15	14	01	03	06		12	50	51	52	11	32	
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PRECAUCIÓN: Papel carbón no es net. Use maquina de escribir o pluma esferografica con tinta negra. No escriba encima de otras formas "MCH". Formas sumajuntas a estas.
 NOTA: No escribe en areas obascurcidas.

Al terminar el estudio, devuelva copia blanca y copia amarilla de esta forma, adjuntas a la forma "A" a: (Retenga copia color de rosa para sus archivos)

M.R. Hilleman, PhD, DSc
 MERCK SHARP & DOHME RESEARCH LABORATORIES
 WEST POINT, PENNSYLVANIA, 19486, U.S.A.

Firma del medico: _____
 Nombre del medico (en letra de molde): _____

Fecha: _____

Table 1

Serological Findings Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:											Initially Seropositive to: Measles Mumps and Rubella		
			Measles-Mumps-Rubella Conversions/Total			Measles-Mumps Conversions/Total		Measles-Rubella Conversions/Total		Mumps-Rubella Conversions/Total		Measles Only Conversions/ Total	Mumps Only Conversions/ Total		Rubella Only Conversions/ Total	
			Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Mumps	Rubella					
10 Months	1	0														
11 Months	2	2	1/1	1/1	1/1			1/1	1/1							
1 Year	29	21	7/7	7/7	7/7			4/5	5/5	3/3	3/3		2/2	3/3		1
2 Years	18	15	3/3	3/3	3/3	1/1	1/1	4/4	4/4	2/3	3/3			3/3		1
3 Years	41	33	6/6	6/6	6/6	1/1	1/1	3/3	3/3	6/6	6/6			14/14		3
4 Years	39	34	2/2	2/2	2/2			5/5	5/5	7/8	8/8	1/1		15/15		3
5 Years	32	25	3/3	2/3	3/3			2/2	2/2	2/3	3/3	2/2		13/13		2
6 Years	36	28	1/1	1/1	1/1			8/8	8/8	2/2	2/2		1/1	15/15		1
7 Years	1	1						1/1	1/1							
Total	199	159	23/23	22/23	23/23	2/2	2/2	28/29	29/29	22/25	25/25	3/3	3/3	63/63		11
Mean Age:	3.7 Years		(100%)	(95.7%)	(100%)			(96.6%)	(100%)	(88.0%)	(100%)			(100%)		

Overall Conversion Rates

Measles	Mumps	Rubella
56/57 (98.2%)	49/53 (92.5%)	140/140 (100%)

Table 2

Serological Findings Among Children Who Received Combined Live
Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:				Initially Seropositive to: Measles and Rubella
			Measles-Rubella Conversions/Total		Measles Only Conversions/ Total	Rubella Only Conversions/ Total	
			Measles	Rubella			
1 Year	22	16	11/11	11/11		4/4	1
2 Years	20	16	7/9	9/9	2/2	3/3	2
3 Years	46	36	14/16	15/16	1/1	13/13	6
4 Years	40	31	5/5	5/5	2/2	20/20	4
5 Years	28	19	5/5	5/5	1/1	11/11	2
6 Years	37	24	7/8	8/8	4/4	9/9	3
Total	193	142	49/54	53/54	10/10	60/60	18
Mean Age: 3.7 Years			(90.7%)	(98.1%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
59/64 (92.2%)	113/114 (99.1%)

4/28/77

Table 3

Distribution of Fold Rises of Hemagglutination-Inhibition Antibody Titers Among Children Who Received Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seropositive			Initially Seronegative			
			Fold Rise		Total	No. Conv.	Failures	Total	Conv. Rate
			>4X	Indet.					
1 Year	13	10		1	1	9		9	9/9
2 Years	17	15		1	1	14		14	14/14
3 Years	30	24		2	2	22		22	22/22
4 Years	38	32	1	1	2	30		30	30/30
5 Years	42	29		3	3	26		26	26/26
6 Years	56	48		8	8	40		40	40/40
7 Years	1	0							
Total	197	158	1	16	17	141	0	141	100%
Mean Age: 4.3 Years									

4/28/77

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella and Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Measles (HI)		Mumps (Neut.)		Rubella (HI)	
Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children
<5		<2	1	<8	
5		2	4	8	
10		4	4	16	
20	2	8	5	32	1
40	5	16	7	64	4
80	5	32	2	128	9
160	6			256	7
320	5			512	2
Total	23		23		23
Geometric Mean Titer	98.8		7.1		148.8

10/3/77

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children
Who Were Initially Seronegative to Measles and Rubella and Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Measles (IU)		Rubella (IU)	
Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children
<5	5	<8	1
5		8	
10	1	16	
20	9	32	1
40	4	64	3
80	22	128	30
160	9	256	13
320	3	512	6
>640	1		
Total	54		54
Geometric Mean Titer	>48.7		151.2

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Rubella and Who Received Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Rubella (HI)	
Post Vaccination Titer	No. of Children
<8	
8	
16	
32	2
64	20
128	70
256	41
<u>>512</u>	8
Total	141
Geometric Mean Titer	<u>>150.5</u>

4/28/77

Table 7

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (199 Children)						Initially Seronegative to: Measles, Mumps and Rubella (23 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	147 (73.9%)	138 (69.3)	160 (81.6)	130 (68.4)	137 (72.5)	83	18 (78.3)	20 (87.0)	23 (100.0)	14 (73.7)	16 (84.2)	16
99 - 100.9	51 (25.6)	57 (28.6)	35 (17.9)	59 (31.1)	52 (27.5)	109	5 (21.7)	3 (13.0)		5 (26.3)	3 (15.8)	7
101 - 102.2		2 (1.0)	1 (0.5)			3						
103 - 104.0	1 (0.5)	2 (1.0)		1 (0.5)		4						
Not Taken			3	9	10				4	4		

Patient # (b) (6)	Temperature	Days	Clinical Complaint	Serology		
				Measles	Mumps	Rubella
	102.2	8	Upper Respiratory Illness, Malaise	>20	320	>8 32 <8 1024
	103.1	20	Irritability, Malaise	>20	160	>8 128 <8 64
	103.1	11	Tonsillitis, Anorexia, Headache, Malaise	>20	>640	<2 4 <8 128
	104.0	1	Irritability, Malaise			Serologies Not Done
	104.0	5	Upper Respiratory Illness, Irritability, Anorexia, Malaise	>20	320	<4 16 <8 256

10/3/77

Table 8

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (193 Children)						Initially Seronegative to: Measles and Rubella (54 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	146 (76.0)	135 (70.3)	138 (72.3)	123 (64.4)	114 (59.7)	67	42 (77.8)	35 (64.8)	39 (72.2)	38 (70.4)	35 (64.8)	23
99 - 100.9	46 (24.0)	56 (29.2)	53 (27.7)	68 (35.6)	77 (40.3)	124	12 (22.2)	19 (35.2)	15 (27.8)	16 (29.6)	19 (35.2)	31
102.0		1 (0.5)				1						
Not Taken	1	1	2	2	2	1						

Serology

Patient #	Temperature	Day	Clinical Complaint	Measles	Rubella
(b) (6)	102.0	5	Upper Respiratory Illness, Irritability, Malaise	>20, 160	>32, 256

4/28/77

Table 9

Maximum Temperatures Reported Among Children Who Received Live
Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (197 Children)					No. with Max. Temp.	Initially Seronegative to: Rubella (141 Children)					No. With Max. Temp.
	Days Post-Vaccination						Days Post-Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	162 (82.2%)	131 (66.5)	148 (75.1)	125 (64.4)	138 (71.5)	67	116 (82.3)	97 (68.8)	110 (78.0)	94 (67.6)	104 (74.8)	51
99-100.9	35 (17.8)	66 (33.5)	48 (24.4)	68 (35.1)	55 (28.5)	128	25 (17.7)	44 (31.2)	30 (21.3)	44 (31.7)	35 (25.2)	88
101 - 102.2			1 (0.5)	1 (0.5)		2			1 (0.7)	1 (0.7)		2
Not Taken				3	4					2	2	

Patient #	Temperature	Day	Clinical Complaint	Serology
(b) (6)	102.2	20	Upper Respiratory Illness, Anorexia, Malaise	<8, 128

4/29/77

Table 10
Clinical Complaints Reported Among Children Who Received Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Clinical Complaint	Total Vaccinees (199 Children)						Initially Seronegative to: Measles, Mumps and Rubella (23 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Irritability	32 (16.1%)	9 (4.5)	2 (1.0)	4 (2.1)		39	5 (21.7)			1 (5.0)		5
Malaise	30 (15.1)	14 (7.0)	3 (1.5)	7 (3.6)	1 (0.5)	43	5 (21.7)	1 (4.3)		2 (10.0)		7
Headache		1 (0.5)	2 (1.0)			2						0
Upper Respiratory Illness	9 (4.5)	11 (5.5)	5 (2.5)	8 (4.1)	5 (2.6)	23	1 (4.3)	1 (4.3)	1 (4.3)	2 (10.0)	1 (5.0)	3
Otitis			2 (1.0)	3 (1.5)		3			1 (4.3)	1 (5.0)		1
Ophthalmopathy		1 (0.5)				1						0
Gastrointestinal Illness	13 (6.5)	7 (3.5)	2 (1.0)	5 (2.6)	1 (0.5)	22		1 (4.3)				1
Anorexia	5 (2.5)	3 (1.5)	2 (1.0)	5 (2.6)		13				1 (5.0)		1
Mild Dermatitis		1 (0.5)				1						0
Persons with Complaints:	49 (24.6)	22 (11.1)	11 (5.5)	19 (9.8)	6 (3.1)	73	6 (26.1)	2 (8.7)	1 (4.3)	4 (20.0)	1 (5.0)	10
Persons with No Complaints:	150 (75.4)	177 (88.9)	188 (94.5)	175 (90.2)	187 (96.9)	123	17 (73.9)	21 (91.3)	22 (95.7)	16 (80.0)	19 (95.0)	12
Negative Physician Surveillance				5	6					3	3	

Table 11

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Clinical Complaint	Total Vaccines (193 Children)						Initially Seronegative to: Measles and Rubella (54 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Irritability	29 (15.1)	11 (5.7)	6 (3.1)	9 (4.7)	6 (3.1)	52	13 (24.1)	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	18
Malaise	33 (17.2)	21 (10.9)	15 (7.9)	15 (7.9)	7 (3.7)	65	12 (22.2)	8 (14.8)	4 (7.4)	2 (3.7)	1 (1.9)	18
Headache	4 (2.1)	3 (1.6)	2 (1.0)	2 (1.0)		9		1 (1.9)	1 (1.9)			1
Upper Respiratory Illness	1 (0.5)	9 (4.7)	8 (4.2)	8 (4.2)	1 (0.5)	21	1 (1.9)	5 (9.3)	2 (3.7)	1 (1.9)		6
Bronchitis			1 (0.5)	1 (0.5)		1			1 (1.9)	1 (1.9)		1
Otitis	1 (0.5)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	6		2 (3.7)	1 (1.9)			3
Gastrointestinal Illness	5 (2.6)	7 (3.6)	6 (3.1)	4 (2.1)	3 (1.6)	23	1 (1.9)	2 (3.7)	1 (1.9)	1 (1.9)		5
Anorexia	5 (2.6)	4 (2.1)	6 (3.1)	4 (2.1)		17	2 (3.7)	1 (1.9)	1 (1.9)			4
Hepatitis	1 (0.5)	1 (0.5)				1						0
Asthma		1 (0.5)				1						0
Persons with Complaints:	36 (18.8)	24 (12.5)	17 (8.9)	18 (9.4)	8 (4.2)	70	13 (24.1)	9 (16.7)	4 (7.4)	3 (5.6)	1 (1.9)	19
Persons with No Complaints:	156 (81.3)	168 (87.5)	174 (91.1)	173 (90.6)	183 (95.8)	121	41 (75.9)	45 (83.3)	50 (92.6)	51 (94.4)	53 (98.1)	35
Negative Physician Surveillance:	1	1	2	2	2	1						

Table 12

Clinical Complaints Reported Among Children Who Received Live
Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-0418 (Study #442)

Clinical Complaint	Total Vaccinees (197 Children)						Initially Seronegative to: Rubella (151 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-62		0-4	5-12	13-18	19-28	29-62	
Irritability	22 (11.2)	4 (2.0)	3 (1.5)	5 (2.6)	2 (1.0)	32	15 (10.6)	4 (2.8)	2 (1.4)	2 (1.4)	1 (0.7)	23
Malaise	28 (14.2)	10 (5.1)	5 (2.5)	9 (4.6)	4 (2.1)	46	19 (13.5)	9 (6.4)	2 (1.4)	5 (3.5)	2 (1.4)	32
Headache	2 (1.0)	1 (0.5)		3 (1.5)	1 (0.5)	6	1 (0.7)			1 (0.7)		2
Upper Respiratory Illness	4 (2.0)	8 (4.1)	1 (0.5)	5 (3.1)	2 (1.0)	15	3 (2.1)	6 (4.3)	1 (0.7)	5 (3.5)	2 (1.4)	13
Otitis	2 (1.0)			2 (1.0)	1 (0.5)	4	1 (0.7)			1 (0.7)	1 (0.7)	2
Ophthalmopathy	1 (0.5)	1 (0.5)				1	1 (0.7)	1 (0.7)				1
Gastrointestinal Illness	5 (2.5)	6 (3.0)	1 (0.5)	1 (0.5)	1 (0.5)	11	4 (2.8)	5 (3.5)	1 (0.7)		1 (0.7)	8
Anorexia	7 (3.6)	1 (0.5)		5 (2.6)		13	4 (2.8)			4 (2.8)		8
Persons with Complaints:	35 (17.8)	18 (9.1)	7 (3.6)	16 (8.2)	7 (3.6)	60	23 (16.3)	14 (9.9)	4 (2.8)	10 (7.1)	5 (3.5)	43
Persons with No Complaints:	162 (82.2)	179 (90.9)	190 (96.4)	180 (91.8)	188 (96.4)	137	118 (83.7)	127 (90.1)	137 (97.2)	131 (92.9)	136 (96.5)	98
Negative Physician Surveillance				1	2							

MEMO

To File Location Date 2/2/78
From T. Schofield Location
Subject Statistical Analysis - Study #442

Analysis of variance was conducted on post titers of children who were initially seronegative to rubella who received rubella vaccine, lot #579 (Group 1), combined measles-mumps-rubella vaccine, lot #621 (Group 2), and combined measles-rubella vaccine, lot #622 (Group 3).

No significant difference exists among the three groups. Geometric mean titers were:

<u>Vaccine</u>	<u>GMT</u>
Rubella	150.5
MMR	143.4
MR	155.5

There is no significant difference in conversion rate among these three groups.



T.S.



Reference No. 2

Program: Study #443

Vaccine: Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine,
Lot No. 621/C-D763Live Attenuated Rubella (RA 27/3) Virus Vaccine,
Lot No. 579/C-D418

Responsible Clinical Investigator:

Robert E. Weibel, M.D.
Director, Division of Preventive Medicine
Joseph Stokes, Jr. Research Institute
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, Pennsylvania 19104

Study Location:

Children's Hospital of Philadelphia
Darby Child Health Clinic, Darby, Pennsylvania
G. Starkweather, M.D., Havertown, Pennsylvania

Date Study Initiated: October 28, 1975

Date Study Completed: January 20, 1977

Study Procedure:

A total of 194 children 10 months to 8 years of age from the open population were included in the study. One hundred ninety-one children received a 0.5 ml subcutaneous dose of one of two vaccines. Three children received a 1.0 ml subcutaneous dose of the combined live measles-mumps-rubella (RA 27/3) virus vaccine. Blood samples were obtained prior to and six weeks after vaccination.

Clinical Protocol - Study #443Combined Live Measles-Mumps-Rubella (RA 27/3) Virus VaccineLive Attenuated Rubella (RA 27/3) Virus Vaccine

Purpose: To determine antibody and clinical responses to combined live measles-mumps-rubella (RA 27/3) virus vaccine and to live attenuated rubella (RA 27/3) virus vaccine.

Vaccines: a) Combined live measles-mumps-rubella (RA 27/3) virus vaccine, lyophilized
Lot No. 621

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

b) Live attenuated rubella (RA 27/3) virus vaccine, lyophilized
Lot No. 579

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single-dose vials. Each vial of vaccine should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: The combined vaccine may contain egg protein and should not be given to persons with known sensitivity to egg, chicken or chicken feathers. Both vaccines contain neomycin and should not be given to persons with known sensitivity to neomycin. Persons with leukemia or other immunologic disorders and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C until used.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: Establish two groups of 50 to 100 children 1 to 6 years of age as follows:

<u>Group</u>	<u>Vaccine</u>	<u>No. Children</u>
Group 1	measles-mumps-rubella	50-100
Group 2	rubella	50-100

Clinical Protocol -
Study #443

-2-

Children in Group 1 will have a negative history for vaccination and illness for measles, mumps, and rubella. Children in Group 2 will have a negative history for rubella vaccination and illness.

Informed consent will be obtained from each child's parent or guardian prior to his participation in the study.

Each child will be bled (10-15 ml) immediately prior to vaccination and 6 weeks following vaccination.

Vaccine dose is 0.5 ml given subcutaneously.

Each child will be followed clinically for 42 days following vaccination. All local and systemic complaints will be recorded on the case report form.

Schedule:	<u>Time</u>	<u>Action</u>
	Day 0	Bleed 10-15 ml. Vaccinate 0.5 ml, subcutaneously.
	Days 0-42	Clinical follow-up for local and systemic reactions.
	Week 6	Bleed 10-15 ml.

Serology: Circulating levels of antibody before and after vaccination will be determined. Measles and rubella antibody levels will be determined by hemagglutination-inhibition test. Mumps antibody levels will be determined by serum neutralization test.

Clinical Forms: Attached.

Adverse Reactions: Any serious or alarming reaction, including death due to any cause during this investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.

Unused Vaccine: All unused vaccine should be returned immediately to the Virus and Cell Biology Laboratories of the Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.



M. R. Hilleman, Ph.D.

FAMILY No. _____ CASE No. _____

CHILD'S NAME _____
LAST FIRST MIDDLE

SEX _____ BIRTHDATE _____ AGE _____ HISTORY: MUMPS _____
 RUBELLA _____

PARENTS NAME _____ TELEPHONE No. _____
LAST FIRST MIDDLE

ADDRESS _____
NUMBER STREET CITY STATE

LOCATION _____

PRE-VACCINATION _____

CLINICAL _____

I consent to have my child, named above, receive live attenuated measles, mumps, rubella virus vaccine.

SIGNATURE _____

DATE _____

VACCINATION: VACCINE _____ LOT 13-16 BLEEDINGS _____

1. DATE 17-22 VOL. _____ SITE _____ PRE-VACCINATION 17-22 CASE No. 5-9
 POST-VACCINATION 28-26

BLEEDING DATE	SEROLOGY									CLINICAL SUMMARY					
	MEASLES			MUMPS			RUBELLA			POST VAC.	MAX. TEMP.	CODE	COMPLETIONS	CODE	CODE
1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3	1 2 3						
TECHNIQUE															
1.										0-4	27-30	01		27-33	28-35
2.										5-12	28-30	00		11-13	02-00
3.										13-18	28-30	00		04-04	07-03
4.										19-28	28-30	00		05-07	01-02
SIGNATURE	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	COMMENTS:				
MEASLES <input type="checkbox"/>															
CLINICAL MUMPS <input type="checkbox"/>															
RUBELLA <input type="checkbox"/>															
Isolation _____															
DATE _____															
Dr. _____															
PHYSICIAN															

SYMPTOM RECORD

M-M-R Study No. _____

CHILD'S NAME _____ CASE NO. _____
(Last) (First) (Middle)

DAY	DATE	Temperature		NONE	RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	THROWING UP	DIARRHEA	STOMACH ACHE	RASH (describe)	SORE JOINTS	SORE ARM (at shot)	HEADACHE	HURTS ALL OVER	FEVER	WON'T EAT	COMMENTS		
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral <i>(Check One)</i>																				
0																							
1																							
2																							
3																							
4																							
5																							
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39																							
40																							
41																							
42																							

if or unusual reaction develops, call:

DR. R. E. WEIBEL
 Havertown, Pennsylvania - Phone: Hilltop 6-1110
 OR
 Children's Hospital of Philadelphia - EV 7-1309

PLEASE RETURN FOR FOLLOW-UP VISIT ON: _____

BE SURE TO BRING THIS RECORD ALONG WITH YOU.

Table 1

Serological Findings Among Children Who Received a 0.5 MI Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:										Initially Seronegative to: Measles Mumps and Rubella			
			Measles-Mumps-Rubella Conversions/Total			Measles-Mumps Conversions/Total		Measles-Rubella Conversions/Total		Mumps-Rubella Conversions/Total		Measles Only Conversions/ Total		Mumps Only Conversions/ Total	Rubella Only Conversions/ Total	
			Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Mumps	Rubella					
(Months) 11	8	6	6/6	6/6	6/6											
(Years) 1	68	64	48/52	50/52	52/52	0/1	1/1	7/7	7/7	2/2	2/2			2/2		
2	10	10	7/7	6/7	7/7	1/1	1/1			2/2	2/2					
3	5	5	3/3	3/3	3/3			1/1	1/1	1/1	1/1					
4	2	2								1/1	1/1	1/1				
5	3	3						1/1	1/1	2/2	2/2					
6	4	4								1/1	1/1			3/3		
7	1	0														
8	1	1														1
Total	102	95	64/68	65/68	68/68	1/2	2/2	9/9	9/9	9/9	9/9	1/1		5/5		1
Mean Age:	1.7 Years		(94.1%)	(95.6%)	(100%)											

Overall Conversion Rate

Measles	Mumps	Rubella
75/80 (93.8%)	76/79 (96.2%)	91/91 (100%)

Table 2

Serological, Temperature and Clinical Findings for 3 Children Who Received a 1.0 ML Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-0763 (Study #443)

Vaccinee No.	Age (Years)	Serology Results			Days Post-Vaccination	Maximum Temperature (°F, Oral)	Clinical Complaints
			Pre	Post			
(b) (6)	3	Measles	Pre	>20	0-4	100.0	Gastrointestinal Illness
			Post	80	5-12	98.6	Gastrointestinal Illness
		Mumps	Pre	>8	13-18	98.6	None Reported
	Post		64	19-28	98.6	None Reported	
	Rubella	Pre	>32	29-42	98.6	None Reported	
		Post	256				
	4	Measles	Pre	<5	0-4	99.4	None Reported
			Post	20	5-12	100.0	Non-Specific Rash, Day 5
		Mumps	Pre	4	13-18	99.8	None
Post	8		19-28	99.7	None		
Rubella	Pre	<8	29-42	99.6	None		
	Post	256					
1	Measles	Pre	<5	0-4	Not Taken	Upper Respiratory Illness, Otitis	
		Post	10	5-12	Not Taken	Otitis	
	Mumps	Pre	<2	13-18	98.6	None Reported	
Post		4	19-28	98.6	None Reported		
Rubella	Pre	<8	29-42	98.6	None Reported		
	Post	32					

Table 3

Serological Findings Among Children Who Received a 0.5 Ml Dose of
Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #443)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seropositive				Initially Seronegative			
			Fold Rise			Total	No. Conv.	Failures	Total	Conv. Rate
			2x	≥4x	Indet.					
(Months)										
10	1	1					1		1	1/1
11	8	8		1		1	7		7	7/7
(Years)										
1	42	41		3	3	6	35		35	35/35
2	13	12			4	4	8		8	8/8
3	11	11			4	4	7		7	7/7
4	9	9			3	3	6		6	6/6
5	3	3	1			1	2		2	2/2
6	1	1					1		1	1/1
7	1	0								
Total	89	86	1	4	14	19	67	0	67	100%
Mean Age:	1.9 Years									

5/4/77

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella and Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Measles (III)		Mumps (Neut.)		Rubella (III)	
Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children
<5	4	<2	3	<8	
5		2	3	8	
10	2	4	16	16	1
20	9	8	26	32	2
40	13	16	8	64	18
80	20	32	11	128	19
160	12	64		256	25
320	7	128	1	512	3
640	1				
Total	68		68		68
Geometric Mean Titer:	57.0		8.2		136.1

5/4/77

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children
Who Were Initially Seronegative to Rubella and Who Received a 0.5 ml Dose
of Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #443)

Rubella (HI)	
Post-Vaccination Titer	No. of Children
<8	
8	
16	1
32	4
64	10
128	21
256	20
≥512	11
Total	67
Geometric Mean Titer:	≥159.1

5/5/77

Table 6

Maximum Temperatures Reported Among Children Who Received a 0.5 Ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Maximum Temperature (°F, Oral)	Total Vaccinees (102 Children)						Initially Seronegative to: Measles, Mumps, and Rubella (68 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	53 (60.9%)	52 (59.1)	71 (83.5)	60 (71.4)	55 (65.5)	32	40 (63.5)	39 (61.9)	52 (83.9)	43 (70.5)	41 (68.3)	23
99 - 100.9	26 (30.0)	22 (25.0)	12 (14.1)	15 (17.9)	20 (23.8)	31	18 (28.6)	14 (22.2)	8 (12.9)	10 (16.4)	14 (23.3)	23
101 - 102.9	7 (8.0)	13 (14.8)	1 (1.2)	5 (5.9)	7 (8.3)	21	5 (7.9)	9 (14.3)	1 (1.6)	4 (6.6)	4 (6.7)	14
103 - 104.9	1 (1.1)	1 (1.1)	1 (1.2)	3 (3.6)	2 (2.4)	6		1 (1.6)	1 (1.6)	3 (4.9)	1 (1.7)	4
105.0				1 (1.2)		1				1 (1.6)		1
Not Taken	15	14	17	18	18	11	5	5	6	7	8	3

5/5/77

Table 7

High Temperatures Reported Among Children Who Received a 0.5 MI Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Vaccinee No.	Temperature (°F, Oral)	Days	Clinical Complaints	Serology					
				Measles		Mumps		Rubella	
				Pre	Post	Pre	Post	Pre	Post
(b) (6)	102.2	5	None Reported (Had Measles-Like Rash Days 7-10)	<5	160	<2	4	<8	64
	102.0	2, 5	URI	<5	20	<2	4	<8	256
	104.0	17	URI, Otitis, Ophthalmopathy, Anorexia, Allergic Rash						
	105.0	23	URI						
	104.0	24	URI						
	102.0	25	URI						
	103.0	27, 32	Teething						
	102.0	33	Teething						
	102.0	32	Anorexia	<5	40	<2	8	16	128
	102.0	10	None Reported	<5	40	<2	4	<8	64
	102.0	9	URI, Irritability, Gastrointestinal Illness	<5	20	<2	16	<8	512
	102.0	35-36	URI	<5	160	>8	>128	<8	256
	102.0	2	URI	<5	<5	<2	2	>32	32
	102.0	7	None Reported (Developed Measles-Like Rash on Day 12)	<5	80	>8	8	<8	128
	102.0	10	URI, Lymphadenopathy, Anorexia	<5	40	>8	8	<8	128
	103.0	7	URI, Otitis, Ophthalmopathy, Gastrointestinal Illness	<5	80	<2	4	<8	256
	102.0	8	URI, Otitis, Ophthalmopathy, Gastrointestinal Illness						
	103.0	28	URI, Otitis, Ophthalmopathy, Lymphadenopathy, Non-Specific Rash on Arms, Legs, Face	<5	80	<2	4	<8	128
	103.0	4	URI, Gastrointestinal Illness	QNS	QNS	QNS	QNS	<8	8
	102.0	0	URI, Anorexia	<5	80	>8	>128	<8	512
	103.0	20-21	Herpes Stomatitis, Anorexia	<5	40	<2	8	<8	256
	102.7	33	URI	<5	<5	<2	8	<8	256
	102.0	3-4	URI	<5	80	<2	8	<8	128
	103.0	24	Gastrointestinal Illness	<5	80	<2	32	<8	256
	103.5	38-42	Allergic Rash	NS	NS	NS	NS	NS	NS

Table 8

Maximum Temperatures Reported Among Children Who Received a 0.5 Ml Dose of
Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/G-0418 (Study #443)

Maximum Temperature (°F, Oral)	Total Vaccinees (89 Children)					No. with Max. Temp.	Initially Seronegative to: Rubella (67 Children)					No. with Max. Temp.
	Days Post-Vaccination						Days Post-Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	54 (70.0%)	53 (69.7)	57 (80.3)	55 (78.6)	57 (83.8)	40	38 (66.7)	37 (66.1)	40 (78.4)	37 (74.0)	37 (77.1)	26
99 - 100.9	19 (24.7)	17 (22.4)	11 (15.5)	8 (11.4)	10 (14.7)	25	16 (28.1)	14 (25.0)	9 (17.6)	8 (16.0)	10 (20.8)	21
101 - 102.9	4 (5.2)	5 (6.6)	2 (2.8)	5 (7.1)	1 (1.5)	10	3 (5.3)	4 (7.1)	1 (2.0)	3 (6.0)	1 (2.1)	8
103 - 104.9		1 (1.3)	1 (1.4)	1 (1.4)		3		1 (1.8)	1 (2.0)	1 (2.0)		3
105.0				1 (1.4)		1				1 (2.0)		1
Not Taken	12	13	18	19	21	10	10	11	16	17	19	8

Table 9

High Temperatures Reported Among Children Who Received a 0.5 Ml Dose of
Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #443)

Vaccine No.	Temperature (°F, Oral)	Days	Clinical Complaints	Serology	
				Pre	Post
(b) (6)	102.2	7-8	None Reported	<8	128
	102.0	23	Upper Respiratory Illness	<8	64
	102.0	36	Upper Respiratory Illness, Otitis, Lymphadenopathy, Myalgia	<8	128
	102.0	6	Upper Respiratory Illness	<8	128
	105.0	24	Pneumonia	<8	64
	102.1	9	Upper Respiratory Illness	>32	>1024
	102.0	18	None Reported		
	102.0	27	None Reported		
	103.0	18	Gastrointestinal Illness, Anorexia	<8	>1024
	104.0	27	Upper Respiratory Illness	<8	512
	103.0	12	Upper Respiratory Illness	<8	256

5/5/77

Table -0

Clinical Complaints Reported Among Children Who Received a 0.5 Ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Clinical Complaint	Total Vaccinees (102 Children)						Initially Seronegative to: Measles, Mumps and Rubella (68 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Soreness at Injection Site	4 (4.2)			1 (1.0)		5	2 (3.0)					2
Lymphadenopathy	2 (2.1)	3 (3.1)		2 (2.1)	2 (2.1)	6	1 (1.5)	1 (1.5)		2 (3.0)	2 (3.0)	3
Measles-Like Rash	1 (1.0)	9 (9.4)	6 (6.2)	1 (1.0)		11	1 (1.5)	7 (10.4)	5 (7.5)	1 (1.5)		9
Arthralgia			1 (1.0)	1 (1.0)		1			1 (1.5)	1 (1.5)		1
Myalgia		1 (1.0)				1		1 (1.5)				1
Irritability	3 (3.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	4	2 (2.9)	2 (2.9)	1 (1.5)	1 (1.5)		3
Headache	2 (2.1)	2 (2.1)				2	2 (3.0)	2 (3.0)				2
Upper Respiratory Illness	38 (39.6)	37 (38.5)	24 (25.0)	35 (36.5)	32 (33.3)	64	28 (41.8)	27 (40.3)	20 (29.8)	25 (37.3)	20 (29.8)	46
Otitis	1 (1.0)	7 (7.3)	2 (2.1)	5 (5.2)	4 (4.2)	14	1 (1.5)	4 (6.0)	2 (3.0)	3 (4.5)	2 (3.0)	9
Ophthalmopathy	2 (2.1)	3 (3.1)	2 (2.1)	4 (4.2)	2 (2.1)	6	2 (3.0)	3 (4.5)	2 (3.0)	4 (6.0)	2 (3.0)	6
Gastrointestinal Illness	18 (18.7)	24 (25.0)	9 (9.4)	17 (17.7)	15 (15.6)	43	14 (20.9)	19 (28.4)	9 (13.4)	14 (20.9)	11 (16.4)	35
Anorexia	13 (13.5)	19 (19.8)	8 (8.3)	10 (10.4)	13 (13.5)	28	10 (14.9)	12 (17.9)	6 (9.0)	9 (13.4)	11 (16.4)	20
Fatigue				1 (1.0)		1				1 (1.5)		1
Rash-Chafing, Diaper, Heat, Herpes	4 (4.2)	4 (4.2)	1 (1.0)	4 (4.2)	5 (5.2)	12	3 (4.5)	4 (6.0)	1 (1.5)	3 (4.5)	3 (4.5)	9
Allergy, Asthma	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)	3 (3.1)	6		1 (1.5)	2 (3.0)	1 (1.5)		3
Fever	1 (1.0)	1 (1.0)		2 (2.1)	1 (1.0)	4		1 (1.5)		1 (1.5)		2
Sudoresis	1 (1.0)					1	1 (1.5)					1
Teething	3 (3.0)			1 (1.0)	3 (3.0)	6	3 (4.4)			1 (1.5)	3 (4.4)	6
Persons with Complaints:	50 (52.1)	50 (52.1)	33 (34.4)	43 (44.8)	44 (45.8)	78	38 (56.7)	38 (56.7)	29 (43.3)	32 (47.8)	30 (44.8)	58
Persons with No Complaints:	46 (47.9)	46 (47.9)	63 (65.6)	53 (55.2)	52 (54.2)	18	29 (43.3)	29 (43.3)	38 (56.7)	35 (52.2)	37 (55.2)	9
Negative Physician Surveillance	6	6	6	6	6	6	1	1	1	1	1	1

Table 11

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-0618 (Study 4443)

Clinical Complaint	Total Vaccinees (89 Children)					No. with Complaint	Initially Seronegative for Rubella (67 Children)					No. with Complaint
	Days Post-Vaccination						Days Post-Vaccination					
	0-4	5-12	13-18	19-28	29-67		0-4	5-12	13-18	19-28	29-67	
Soreness at Injection Site	7 (8.4)					7	6 (9.5)					6
Lymphadenopathy		1 (1.2)		1 (1.2)	1 (1.2)	3		1 (1.6)		1 (1.6)	1 (1.6)	3
Rubella-Like Rash		2 (2.4)	1 (1.2)			3		2 (3.2)	1 (1.6)			3
Arthralgia	1 (1.2)				1 (1.2)	1	1 (1.6)				1 (1.6)	1
Myalgia	1 (1.2)		1 (1.2)	1 (1.2)	1 (1.2)	3	1 (1.6)		1 (1.6)	1 (1.6)	1 (1.6)	3
Irritability	1 (1.2)	3 (3.6)		1 (1.2)	2 (2.4)	5	1 (1.6)	3 (4.8)		1 (1.6)	2 (3.2)	5
Headache	3 (3.6)	2 (2.4)		2 (2.4)		6	3 (4.8)	1 (1.6)		2 (3.2)		5
Upper Respiratory Illness	30 (38.1)	23 (27.7)	13 (15.7)	16 (18.9)	15 (18.1)	45	24 (38.1)	18 (28.6)	9 (14.3)	12 (19.0)	12 (19.0)	37
Lower Respiratory Illness				1 (1.2)		1				1 (1.6)		1
Otitis	1 (1.2)	5 (6.0)	1 (1.2)	1 (1.2)	3 (6.0)	10	1 (1.6)	4 (6.3)	1 (1.6)	1 (1.6)	5 (7.9)	9
Ophthalmopathy	1 (1.2)	1 (1.2)	3 (3.6)	2 (2.4)	1 (1.2)	4	1 (1.6)	1 (1.6)	2 (3.2)	1 (1.6)	1 (1.6)	3
Gastrointestinal Illness	12 (14.5)	11 (13.3)	8 (4.8)	9 (10.8)	10 (12.0)	30	11 (17.5)	9 (14.3)	6 (6.3)	7 (11.1)	7 (11.1)	25
Anorexia	12 (14.5)	8 (9.6)	7 (8.4)	6 (7.2)	5 (6.0)	16	9 (14.3)	7 (11.1)	6 (9.5)	5 (7.9)	4 (6.3)	13
Fatigue			1 (1.2)			1			1 (1.6)			1
Rash-Chafing, Diaper, Heat	10 (12.0)	6 (7.2)	5 (7.2)	7 (8.4)	4 (6.0)	15	8 (12.7)	5 (7.9)	5 (7.9)	6 (9.5)	4 (6.3)	13
Allergy, Asthma	2 (2.4)	1 (1.2)	2 (2.4)	1 (1.2)	2 (2.4)	3	1 (1.6)	1 (1.6)	2 (3.2)	1 (1.6)	2 (3.2)	2
Fever					1 (1.2)	1					1 (1.6)	1
Depression		1 (1.2)				1		1 (1.6)				1
Teething		1 (1.2)	1 (1.2)	1 (1.2)	1 (1.2)	2		1 (1.6)	1 (1.6)	1 (1.6)	1 (1.6)	2
Impetigo, Mosquito Bites			1 (1.2)	1 (1.2)		2			1 (1.6)	1 (1.6)		2
Persons with Complaints:	30 (69.2)	37 (44.6)	29 (34.9)	31 (37.3)	31 (37.3)	45	39 (61.9)	30 (67.6)	24 (38.1)	27 (42.9)	28 (41.3)	53
Persons with No Complaints:	33 (39.8)	46 (55.4)	54 (65.1)	52 (62.7)	52 (62.7)	18	24 (38.1)	33 (52.8)	39 (61.9)	36 (57.1)	37 (58.7)	10
Negative Physician Surveillance:	6	6	6	6	6	6	4	6	4	4	4	6

CLINICAL SUMMARY

Study Name - Combined Live Measles-Mumps-Rubella (RA 27-3) Virus Vaccine and Live Rubella (RA 27/3) Virus Vaccine

Study Number - Clinical Protocol - 443

Material - M-M-R Lot #621/C-D763
Rubella Lot #579/C-D418

Initiated - October 28, 1975

Completed - January 20, 1977


Medical Opinion

For 15 months 194 children (ages 10 months to 8 years) from the open population were enrolled in this study at Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; Darby Health Clinic, Darby, Pennsylvania; and Dr. G. Starkweather's office, Havertown, Pennsylvania. Informed consent was obtained from the parent for each child and a blood sample was obtained from 184 children initially and approximately 6 weeks later. All vaccine was given subcutaneously in the arm. One hundred and two children (mean 1.7 years) received 0.5 ml. M-M-R; 3 (mean 2.7 years) received 1.0 ml. M-M-R; and 89 children (mean 1.9 years) received 0.5 ml. rubella vaccine. All but 12 parents returned report cards with daily temperatures and clinical observations for 42 days following administration of the vaccine. Parents were instructed to report high fevers and rash by telephone to R. E. W. and on follow-up were queried on recorded observations for greater detail.

Among susceptible and immune vaccinees temperature elevations were scattered randomly throughout the observation period with no greater association with either vaccine. Most temperature elevations probably reflect unrelated infection occurring among the vaccinees at various time periods. Upper respiratory and gastrointestinal infections were reported in about 55% and 40% of vaccinees respectively. Temperatures were not recorded on approximately 10% of the vaccinees. A faint measles-like rash occurred in 9 triple susceptible children receiving M-M-R and 3 susceptibles receiving rubella vaccine alone. Mild transient arthralgia was reported by the parent but not observed by a medical person in one M-M-R susceptible vaccinee, age 12 months, on day 17-20 (4 days); and one rubella susceptible vaccinee age 5 years on day one and 30 (2 days). No arthritis or adverse clinical reaction was reported.

Of 68 children initially susceptible to measles-mumps-rubella receiving 0.5 ml. M-M-R vaccine 94%, 96%, and 100% respectively, responded serologically with geometric mean titers as follows: measles (HI) 57.0; mumps (neut.) 8.2; and rubella (HI) 136.1. All 67 rubella susceptible vaccinees responded serologically with a geometric mean hemagglutination titer equal to or greater than 159.1. Of the three children receiving 1.0 ml. M-M-R, all susceptibles responded, however, one was initially immune to M-M-R and one to mumps.

Seroconversion of susceptible children to rubella vaccine alone or in combined M-M-R was 100% with comparable hemagglutination inhibiting geometric mean titers. Seroconversion rates and geometric mean titers to measles and mumps vaccine following M-M-R (RA 27/3) are similar to those following M-M-R (HPV-77) reported in earlier studies. Live RA 27/3 rubella virus vaccine alone or combined with live measles and live mumps virus vaccine induced measureable antibodies in all rubella susceptible vaccinees with no significant clinical reaction.

Jan 27, 1977 
Robert E. Weibel, M.D.

MEMO

To File Location Date 2/2/78
From T. Schofield Location
Subject Statistical Analysis - Study #443

Analysis of variance was conducted on post titers of children who were initially seronegative to rubella who received rubella vaccine, lot #579 (Group 1), and combined measles-mumps-rubella vaccine, lot #621 (Group 2).

No significant difference exists between these two groups. Geometric mean titers were:

<u>Vaccine</u>	<u>GMT</u>
Rubella	159.1
MMR	130.9

There is no significant difference in conversion rate among these two groups.


T.S.



SYMPTOM RECORD
RUBELLA Study No. _____

LD'S NAME _____ CASE NO. _____
(Last) (First) (Middle)

DAY	DATE	Temperature		RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	THROWING UP	DIARRHEA	STOMACH ACHE	RASH (desc/loc)	SORE JOINTS	SORE ARM (at spot)	HEADACHE	HURTS ALL OVER	FEVER	WON'T EAT	COMMENTS		
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral <i>(Check One)</i>																			
0																						
1																						
2																						
3																						
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40																						

with combination vaccines.

INFORMATION AND CONSENT FORM: Attached

REACTION REPORTING FORM: Attached

Stephen J. Lerman, M.D.
Director - Pediatric Infectious Disease Unit
University of Nebraska Medical Center

11/30/76

THE UNIVERSITY OF NEBRASKA MEDICAL CENTER
42ND AND DEWEY AVENUE
OMAHA, NEBRASKA 68105

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Lee Matthews, Ph.D.
Susan Osborn, M.S.

April 11, 1978

To: Measles-Mumps-Rubella Vaccine Study Participants
From: Jan Brunken RN
Pediatric Infectious Disease Unit
Subject: March M-M-R Vaccine Study Progress Report

Here is the current breakdown of the numbers of children participating in the study to date (March 31):

	<u>Entered</u>	<u>Completed</u>
Zahller	9	9
Nelson/Rice	2	2
Wax/McAveney	13	13
Ellison/Glow/Oberst	2	2
Maragos	0	0
Pott, Co. Immun. Clinic	19	18
Offutt AFB	147	97
UNMC Pediatric Clinic	53	36
Cogley Clinic	11	7
UNMC-South Omaha Clinic	0	0
UNMC-5 North	1	1
Total	257	185

Our goal for the month of April is to pass the halfway mark of 275 children enrolled in the study!

Reference 3

Program: Study #459 - To evaluate and compare clinical and immunological responses to two combined measles-mumps-rubella virus vaccines and component vaccines of these.

Vaccine: Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #60664/C-E810
Combined live measles-mumps-rubella (HPV-77) virus vaccine
M-M-R
Live attenuated RA 27/3 rubella virus vaccine
Lot #60151/C-E665
Live attenuated HPV-77 + 5 duck embryo cell passages rubella virus vaccine
MERUVAX
Live measles virus vaccine
ATTENUVAX
Live mumps virus vaccine
MUMPSVAX
Rubella placebo

Responsible Clinical Investigator:

Stephen J. Lerman, M.D.
Assistant Professor of Pediatrics
and Medical Microbiology
Director, Pediatric Infectious Disease Unit
42nd Street and Dewey Avenue
Omaha, Nebraska 68105

Study Locations:

F. Marshall Zahller, M.D., Omaha, Nebraska
Larry Rice, M.D., Paul J. Nelson, M.D., Omaha, Nebraska
James I. Wax, M.D., Omaha, Nebraska
Joseph R. Ellison, M.D., Omaha, Nebraska
George D. Maragos, M.D., Omaha, Nebraska
Mark B. Horton, M.D., Outpatient Clinic, University of
Nebraska Medical Center, Omaha, Nebraska
Colonel James Hart, M.D., Burt Culpepper, M.D., Offutt Air
Force Base, Omaha, Nebraska
William J. McAveney, M.D., Omaha, Nebraska
Donald T. Glow, M.D., Byron B. Oberst, M.D., Omaha
Children's Clinic, Omaha, Nebraska
Yuksel Inankur, M.D., Izzat Jabro, M.D., Dennis Jones, M.D.,
C. Edwards, M.D., Jim Mulry, M.D., Anthony Romano, M.D.,
Cogley Clinic, Council Bluffs, Iowa
Pottawattamie County Immunization Clinic, Lee Martin Therapy
Center, Council Bluffs, Iowa

Date Study Initiated: May 31, 1977

Date Study Completed: In Progress

Study Procedure:

To date, 257 children have entered the study. Each received a 0.5 ml subcutaneous dose of one of the vaccines. Blood samples were obtained on the day of vaccination and 6 weeks after vaccination, at which time each child received vaccine with those components not in the initial injection. Each child was followed 6 weeks for clinical complaints.

COMPARISON OF MEASLES - MUMPS - RUBELLA (HPV-77:DE-5 and RA 27/3)

VACCINES IN YOUNG CHILDREN

PURPOSE

This study will compare antibody and clinical responses in young children to live, attenuated measles, mumps, and rubella vaccines, given singly and together, utilizing either HPV-77:DE-5 or RA 27/3 as the rubella components.

BACKGROUND

HPV-77:DE-5 rubella vaccine was licensed in 1969 and is the most widely-used rubella vaccine in the United States. Although HPV-77:DE-5 vaccinees appear to be protected against viremia and fetal infection, HPV-77:DE-5 vaccine has been criticized because up to 80% of vaccinees may experience asymptomatic re-infection (antibody titer boost and pharyngeal virus excretion) on exposure to wild rubella virus. In comparison with natural rubella infection the serum antibody response to HPV-77:DE-5 is quantitatively and qualitatively diminished, and secretory antibody is lacking. RA 27/3 rubella vaccine has been proposed as a better immunizing agent because the serum and secretory antibody responses more closely resemble natural rubella infection, and because the rate of asymptomatic re-infection on exposure to wild rubella virus is almost as low as that seen in naturally immune subjects. In addition, RA 27/3 rubella vaccine, grown in human tissue culture, should obviate any problem of allergy to foreign protein. Both rubella vaccines have shown similar age-dependent rates of arthralgia and arthritis.

VACCINES

Vaccines will be supplied in single-dose, coded vials by Merck Sharp & Dohme. Measles (Attenuvax), mumps (Mumpsvax), rubella (Meruvax), and the combination of the three (M-M-R) are licensed products. RA 27/3 rubella virus was originally isolated in Dr. Stanley Plotkin's laboratory from the third

-2-

explant of the 27th fetus aborted because of rubella infection during the 1964 epidemic. It has been attenuated by (b) (4) in WI-38 human diploid fibroblast tissue culture.

The lot of vaccine to be used has been fully tested for potency and safety at the Merck Sharp & Dohme Research Laboratories. Vaccine dose is 0.5 ml. given subcutaneously. Dried vaccine should be stored at -20° C (freezer) until used. Reconstituted vaccine should be kept at 4° C (refrigerator), and unused rehydrated vaccine should be discarded after four hours.

STUDY POPULATION

Children one through four years of age who have a negative history of measles, mumps, and rubella, both disease and vaccination, will be recruited by their private or clinic physician at the time they are due to receive these vaccinations.

CAUTION

Any child in the following categories should not be vaccinated.

1. Known sensitivity to chicken or duck, chicken or duck eggs or feathers, or to neomycin.
2. Leukemia or other malignancies, immunologic disorders, immunosuppressive or steroid therapy.
3. Current febrile illness. (Children with non-febrile upper respiratory infection may be vaccinated).

STUDY PROCEDURE

After informed consent has been obtained, an 8-10 cc blood sample will be drawn and children will be randomly assigned to receive one of the following:

<u>Vaccine</u>	<u>No. of Children</u>
Measles-Mumps-HPV-77:DE-5 Rubella	150
Measles-Mumps-RA 27/3 Rubella	150
Measles	50
Mumps	50

<u>Vaccine</u>	<u>No. of Children</u>
HPV-77/DE-5 Rubella	50
RA 27/3 Rubella	50
Placebo	50
Total	550

The parent will be given a reaction reporting form and a thermometer and will be instructed in taking temperatures. They will be asked to take daily temperatures and record all symptoms which occur during the following six weeks.

Six weeks after vaccination, children will return for a second 8-10 cc. blood sample. At this time, reaction reporting forms will be reviewed with the parent and collected. All children will then receive the standard measles, mumps, and rubella vaccine to assure immunization for all three diseases.

SEROLOGIC STUDIES

Participating physicians will refrigerate blood samples which will be picked up by messenger three times a week. Serum will be separated, with an aliquot sent to Merck Sharp & Dohme for rubella precipitin antibody testing and the remainder retained for rubella and measles hemagglutination inhibition antibody and mumps neutralization antibody testing in the University of Nebraska Medical Center Virus Laboratory of Dr. Roberta White.

DATA ANALYSIS

We will compare symptoms (e.g. rash, fever, arthralgia), seroconversion rates and geometric mean titers in children who received combination vaccines, individual component vaccines, or placebo. We will look specifically for evidence of either enhanced reactogenicity or diminished serologic responsiveness

Table 1
Seroconversions and Geometric Mean Titers for Children
Who Were Initially Seronegative Prior to Vaccination (Study #459)

Vaccine	Age		Measles	Mumps	Rubella
	Range	Mean	No. Conv./Total (GMT)	No. Conv./Total (GMT)	No. Conv./Total (GMT)
ATTENUVAX	14m - 3y	1.5	6/6 (90)		
MUMPSVAX	14m - 4y	1.7		11/12 (12)	
RUBELLA (HPV-77)	14m - 2y	1.4			6/7 (95)
RUBELLA (RA 27/3)	14m - 4y	1.6			11/11 (199)
M-M-R (HPV-77)	14m - 4y	1.5	20/20 (77)	20/20 (14)	20/20 (111)
M-M-R (RA 27/3)	14m - 4y	1.6	13/14 (62)	13/14 (17)	14/14 (269)

Statistical nonparametric comparison shows no suppression of post-vaccination antibody titer of any component when administered in combined form with rubella RA 27/3 or HPV-77.

4/20/78

Table 2

Completed Serology for Children
Receiving ATTENUVAX, Study #459

<u>Case #</u>	<u>Measles HI</u>	
	<u>Pre</u>	<u>Post</u>
(b)(8)	<5	80
	<5	
	<5	
	<5	
	<5	40
	<5	80
	<5	160
	<5	160
	<5	80

4/19/78

Table 3

Completed Serology for Children
Receiving MUMPSVAX, Study #459

<u>Case #</u>	<u>Mumps Neut.</u>	
	<u>Pre</u>	<u>Post</u>
(b)(6)	<2	<2
(b)(6)	<2	>64
(b)(6)	<2	4
(b)(6)	<2	64
(b)(6)	<2	
(b)(6)	4	8
(b)(6)	<2	32
(b)(6)	<2	2
(b)(6)	<2	16
(b)(6)	2	8
(b)(6)	<2	8
(b)(6)	<2	16
(b)(6)	<2	32
(b)(6)	<2	8
(b)(6)	<2	16

4/19/78

Table 4

Completed Serology for Children
Receiving Rubella (HPV-77), Study #459

<u>Case #</u>	<u>Rubella HI</u>	
	<u>Pre</u>	<u>Post</u>
(b) (6)		<8
	<8	
	<8	>512
	<8	128
	<8	>512
	<8	128
	<8	>512
	<8	32
	<8	>512
	<8	<8

4/19/78

Table 5

Completed Serology for Children
Receiving Rubella (RA 27/3), Study #459

<u>Case #</u>	<u>Rubella HI</u>	
	<u>Pre</u>	<u>Post</u>
(b) (6)	<8	128
(b) (6)	<8	256
(b) (6)	<8	128
(b) (6)	<8	64
(b) (6)	<8	>512
(b) (6)	<8	64
(b) (6)	<8	>512
(b) (6)	<8	>512
(b) (6)	<8	64
(b) (6)	<8	>512
(b) (6)	256	>512
(b) (6)	<8	256
(b) (6)	<8	>512
(b) (6)	<8	64

4/20/78

Table 6

Completed Serology for Children
Receiving M-M-R (HPV-77), Study #459

Case #	Measles HI		Mumps Neut.		Rubella HI	
	Pre	Post	Pre	Post	Pre	Post
(b) (6)	<5	160	<2	16	<8	256
	<5		<2		<8	
		64		160		8
	<5	>320	<2	8	<8	256
		160	<2			64
	<5	80	<2	4	<8	256
	<5	20	2	>64	<8	256
	<5	160	<2	>64	<8	64
	<5		<2		<8	
	<5	40	<2	64	<8	64
	<5	20	<2	16	<8	256
	<5	40	<2	32	<8	64
	<5	160	<2	16	<8	256
	<5	160	<2	16	<8	128
	<5	40	<2	4	<8	16
		80		32		64
	<5	80	<2	8	8	32
	QNS	QNS	QNS	QNS	<8	128
	<5	80	<2	QNS	<8	64
	QNS	120	QNS	32	<8	>512
	<5	80	<2	32	<8	256
	<5		<4*		<8	
	<5		<2		<8	
	<5	40	<2	16	<8	256
	<5	80	<2	8	<8	64
	<5		<2		<8	
	<5	80	<2	8	<8	>512
	<5		<2		<8	
	<5	160	2	>64	<8	128
	<5		QNS		<8	
	<5	40	<2	4	<8	32
	<5	160	<2	4	<8	64
	<5	160	<2	32	<8	128
	<5	40	<2	32	<8	>512
	<5	40	<2	32	<8	16

* Toxicity at 1:2 level

4/20/78

Table 7

Completed Serology for Children
Receiving M-M-R (RA 27/3), Study #459

Case #	Measles HI		Mumps Neut.		Rubella HI	
	Pre	Post	Pre	Post	Pre	Post
(b) (6)	<5	<5	<2	16	<8	256
	<5	160	<2	64	<8	256
	<5	20	8	8	<8	256
	<5	40	<2	<2	<8	256
	<5	80	<2	4	<8	128
	80	20	<2	4	<8	128
	<5	20	<2	16	<8	256
	<5	40	2	32	<8	>512
	<5	160	4	4	256	>512
	<5	20	QNS	8	<8	256
	<5	160	<2	16	<8	256
	<5	80	<4*	32	<8	128
	<5	80	QNS	<4*	<8	8
	<5	80	<2	>64	<8	>512
	<5	QNS	<2	QNS	<8	256
	<5	160	<2	32	<8	>512
	<5	160	<2	16	<8	256
	<5	>320	<2	16	<8	128
	<5	40	<2	8	<8	>512
		80		8		256
	<5	80	<2	>64	<8	>512
	80	80	QNS	16	32	>512
	<5	40	>64	>64	<8	256
	<5	40	<2	16	<8	256
	<5		16		<8	
	<5		<2		<8	
	QNS		QNS		<8	
	<5	QNS	<2	QNS	<8	8

* Toxicity at 1:2 level

4/20/78

Table 8

Maximum Temperatures Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #80864/C-2810 (Study #459)

Maximum Temperature (°F, Oral)	Total Vaccinees (41 Children)						Initially Seronegatives (16 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	33 (80.5X)	32 (78.0)	34 (82.9)	32 (78.0)	30 (75.0)	17	13 (81.3)	12 (75.0)	14 (87.5)	10 (62.5)	13 (86.7)	7
99 - 100.9	7 (17.1)	3 (7.3)	2 (4.9)	4 (9.8)	3 (7.5)	4	3 (18.8)	2 (12.5)	1 (6.3)	3 (18.8)	1 (6.7)	2
101 - 102.9	1 (2.4)	5 (12.2)	3 (7.3)	3 (7.3)	5 (12.5)	14		2 (12.5)		2 (12.5)	1 (6.7)	5
103 - 104.9		1 (2.4)	2 (4.9)	2 (4.9)	1 (2.5)	6			1 (6.3)	1 (6.3)		2
Fever - No Temperature Taken					1 (2.5)							
Temperature Not Taken					1						1	

Case No. (b) (6)	Max. Temp.	Days	Clinical Complaint	Serology					
				Measles		Mumps		Rubella	
	103.0	20-21	Upper Respiratory Illness, Gastrointestinal Illness	<5	160	<2	64	<8	256
	103.0	36	Gastrointestinal Illness						
	102.0	11-12	Upper Respiratory Illness, Gastrointestinal Illness						
	102.4	24-25	Upper Respiratory Illness, Nonspecific Rash, Anorexia						
	102.2	40-41	Upper Respiratory Illness, Ophthalmopathy, Anorexia, Irritability, Teething	<5	20	8	8	<8	256
	103.0	13-17	Upper Respiratory Illness, Anorexia						
	102.1	10-11	Upper Respiratory Illness, Anorexia	<5	80	<2	4	<8	128
	102.0	11-12	None	<5	20	QNS	8	<8	256
	103.0	5-12	Upper Respiratory Illness, Gastrointestinal Illness, Anorexia, Measles-Like Rash	<5	80	QNS	<4	<8	8
	102.0	39-42	Upper Respiratory Illness, Otitis, Gastrointestinal Illness						
	102.3	24	Upper Respiratory Illness, Anorexia	<5	80	<2	>64	<8	>512
	102.2	38-39	Anorexia	<5	QNS	<2	QNS	<8	8
	102.6	17-18	Upper Respiratory Illness, Gastrointestinal Illness, Anorexia	NS	80	NS	8	NS	256
	102.8	0-4	Upper Respiratory Illness, Ophthalmopathy, Anorexia, Herpes-Type Rash, Soreness at Injection Site	<5	40	>64	>64	<8	256
	104.5	15	Otitis	<5	40	<2	16	<8	256
	103.8	22	Upper Respiratory Illness, Gastrointestinal Illness, Anorexia						

Table 9

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-ER10 (Study #459)

Clinical Complaint	Total Vaccinees (41 Children)					No. with Complaint	Initially Seronegatives (16 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site: Soreness	2 (4.92)					2						0
Systemic: Measles-Like Rash		4 (9.8)	2 (4.9)			5			1 (6.3)			1
Irritability	1 (2.4)	3 (7.3)	2 (4.9)		3 (7.5)	6	1 (6.3)				1 (6.7)	2
Anorexia	8 (19.5)	5 (12.2)	8 (19.5)	9 (22.0)	7 (17.5)	20	3 (18.8)	1 (6.3)	2 (12.5)	3 (18.8)	3 (20.0)	6
Disturbed Sleep		1 (2.4)				1		1 (6.3)				1
Upper Respiratory Illness	16 (39.0)	17 (41.5)	10 (24.4)	11 (26.8)	16 (40.0)	28	5 (31.3)	5 (31.3)	2 (12.5)	6 (37.5)	7 (46.7)	10
Otitis		2 (4.9)	1 (2.4)	3 (7.3)	3 (7.5)	8		1 (6.3)	1 (6.3)	2 (12.5)	1 (6.7)	4
Ophthalmopathy	3 (7.3)	1 (2.4)			3 (7.5)	7		1 (6.3)				1
Gastrointestinal Illness	9 (22.0)	9 (22.0)	6 (14.6)	10 (24.4)	9 (22.5)	24	3 (18.8)	1 (6.3)	2 (12.5)	5 (31.3)	3 (20.0)	10
Nonspecific Rash	2 (4.9)	4 (9.8)	2 (4.9)	3 (7.3)	3 (7.5)	5	1 (6.3)	2 (12.5)	2 (12.5)	2 (12.5)	1 (6.7)	3
Varicella				1 (2.4)		1				1 (6.3)		1
Allergy		1 (2.4)				1		1 (6.3)				1
Teething	1 (2.4)	3 (7.3)	1 (2.4)	1 (2.4)	2 (5.0)	4	1 (6.3)	1 (6.3)	1 (6.3)	1 (6.3)	1 (6.7)	1
Herpes-Type Rash	1 (2.4)					1						0
Persons with Complaint:	20 (48.8)	26 (63.4)	18 (43.9)	16 (39.0)	22 (55.0)	34	7 (43.8)	8 (50.0)	6 (37.5)	8 (50.0)	9 (60.0)	14
Persons with No Complaint:	21 (51.2)	15 (36.6)	23 (56.1)	25 (61.0)	18 (45.0)	7	9 (56.3)	8 (50.0)	10 (62.5)	8 (50.0)	6 (40.0)	2
Negative Surveillance					1						1	

Reference No. 4

Program: Study #467 - To compare antibody and clinical responses to combined live measles-mumps-rubella virus vaccine containing the RA 27/3 rubella virus strain or the HPV-77 duck rubella virus strain.

Vaccine: Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #621/C-D763

Combined live measles-mumps-rubella (HPV-77) virus vaccine
M-M-R

Responsible Clinical Investigator:

Robert E. Weibel, M.D.
Director, Division of Preventive Medicine
Joseph Stokes, Jr. Research Institute
Children's Hospital of Philadelphia
34th and Civic Center Boulevard
Philadelphia, Pennsylvania 19104

Study Locations:

De La Wair Clinic, Wilmington, Delaware
The Northeast Clinic, Wilmington, Delaware
The Riverside Health Clinic, Riverside, New Jersey
The Deborah Clinic, Browns Mill, New Jersey
The Mt. Holly Clinic, Mt. Holly, New Jersey
G. Starkweather, M.D., Havertown, Pennsylvania
E. M. Craven, M.D., Wilmington Medical Center, Wilmington,
Delaware
James W. Williams State Service Center, Dover, Delaware
Lankenau Hospital, Philadelphia, Pennsylvania
Children's Clinic of Chester and Vicinity, Chester,
Pennsylvania

Date Study Initiated: June 7, 1976

Date Study Completed: May 12, 1977

Study Procedure:

Two hundred seventy-five children, 10 months to 7 years of age, from the open population, were included in the study. Two hundred fifty-five children received a 0.5 ml subcutaneous dose of 1 of 2 vaccines. Twenty children received a 1.0 ml subcutaneous dose of combined live measles-mumps-rubella (RA 27/3) virus vaccine. Blood samples were obtained prior to and 6 weeks after vaccination from approximately one half of the children. Each child was followed 6 weeks for clinical complaints.

Clinical Protocol - Study #467Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Purpose: To compare antibody and clinical responses to combined live measles-mumps-rubella virus vaccine containing the RA 27/3 rubella virus strain or the HPV-77 duck rubella virus strain.

Vaccines: 1. Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #621

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

2. Combined live measles-mumps-rubella (HPV-77 duck) virus vaccine
Lot #0131V

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial of vaccine should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: Both vaccines contain egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. The vaccines also contain neomycin and should not be given to persons with sensitivity to neomycin. Persons with leukemia or other immunologic disorders and persons receiving immunosuppressive drugs should not be vaccinated. The vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of children 1 to 4 years old having a negative history of vaccination for and illness caused by measles, mumps and rubella. Children will be randomly assigned to receive one of the two vaccines as follows:

<u>Group</u>	<u>Vaccine</u>	<u>No. of Children</u>
Group 1	M-M-R (RA 27/3)	100-200 children
Group 2	M-M-R (HPV-77 duck)	100-200 children

Clinical Protocol -
Study #467

-2-

Informed written consent will be obtained from each child's parent or guardian prior to his participation in the study.

Each child will receive a single 0.5 ml subcutaneous injection of one of the two combined live measles-mumps-rubella virus vaccines.

Bleeding samples (10-15 ml) will be obtained from approximately one-third of the study participants. They will be bled immediately prior to vaccination and 6-8 weeks following vaccination.

Each child will be followed clinically for 42 days following vaccination. All local and systemic complaints will be recorded on the case report form.

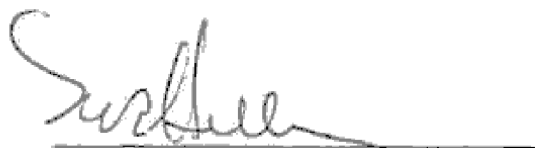
Schedule:	<u>Time</u>	<u>Vaccination and Follow-up (All Children)</u>	<u>Bleeding (Approx. 1/3 of Children)</u>
	Day 0	Vaccinate 0.5 ml, subcutaneously.	Bleed 10-15 ml.
	Days 0-42	Clinical follow-up for local and systemic reactions.	--
	Week 6-8	--	Bleed 10-15 ml.

Serology: Circulating levels of antibody before and after vaccination will be determined. Measles and rubella antibody levels will be determined by hemagglutination-inhibition test. Mumps antibody levels will be determined by serum neutralization test.

**Clinical
Forms:** Attached.

**Adverse
Reactions:** Any serious or alarming reaction, including death due to any cause during this investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.

**Unused
Vaccine:** All unused vaccine should be returned immediately to the Virus and Cell Biology Laboratories of the Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.


M. R. Hilleman, Ph.D.

SYMPTOM RECORD

M-M-R Study No. _____

CHILD'S NAME _____ CASE NO. _____
(Last) (First) (Middle)

DAY	DATE	Temperature		NONE	RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	THROWING UP	DIARRHEA	STOMACH ACHE	RASH (describe)	SORE JOINTS	SORE ARM (at shot)	HEADACHE	HURTS ALL OVER	FEVER	WON'T EAT	COMMENTS		
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral																				
0																							
1																							
2																							
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or or unusual reaction develops, call:

DR. R. E. WEIBEL
 Havertown, Pennsylvania - Phone: Hilltop 6-1110
 OR
 Children's Hospital of Philadelphia - EV 7-1309

PLEASE RETURN FOR FOLLOW-UP VISIT ON: _____

BE SURE TO BRING THIS RECORD ALONG WITH YOU.

INSTRUCTIONS TO PARENT:

1. Please fill in the date each day.
2. Please take temperature once daily at the same time and record exact thermometer reading.
3. If no symptoms are present, place a check (✓) under "NONE" beside that day's date.
4. If a symptom is present, place a check (✓) under it beside that day's date.
5. Describe other symptoms and any RASH in the space under "COMMENTS."
6. THIS IS VERY IMPORTANT INFORMATION. *Please do not misplace this card.*

FAMILY No. _____ CASE No. _____

CHILD'S NAME _____
LAST FIRST MIDDLE

SEX _____ BIRTHDATE _____ AGE _____ HISTORY: MUMPS _____
RUBELLA _____

PARENTS NAME _____ TELEPHONE No. _____
LAST FIRST MIDDLE

ADDRESS _____
NUMBER STREET CITY STATE

LOCATION _____
PRE-VACCINATION _____
CLINICAL _____

I consent to have my child, named above, receive live attenuated measles, mumps, rubella virus vaccine.

SIGNATURE _____
DATE _____

VACCINATION: VACCINE _____ LOT _____ BLEEDINGS _____
 1. DATE _____ VOL. _____ SITE _____ PRE-VACCINATION _____ CASE No. _____
 POST-VACCINATION _____

BLEEDING DATE	SEROLOGY									CLINICAL SUMMARY					
	MEASLES			MUMPS			RUBELLA			POST VAC	WAB. TEMP.	CODE	COMPLAINTS	CODE	CODE
1 2 3	1	2	3	1	2	3	1	2	3	DAYS					
TECHNIQUE										0-4					
1.										27-30	31			33-33	34-35
2.										5-12				41-42	43-44
3.										13-18				50-51	52-53
4.										19-28				58-59	61-62
SUMMARY	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST					

COMMENTS:

Table 1

Serological Findings Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:								Initially Seropositive to:	
			Measles-Mumps-Rubella			Measles-Rubella		Mumps-Rubella		Mumps Only	Rubella Only	Measles Mumps and Rubella
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/Total	Conversions/Total	
Measles	Mumps	Rubella	Measles	Rubella	Mumps	Rubella	Total	Total				
(Months) 11	8	7	6/7	7/7	7/7							
(Years) 1	63	32	29/30	30/30	30/30	0/1	1/1	1/1	1/1			
2	17	10	7/8	7/8	8/8			1/1	1/1	1/1		
3	11	6						1/1	1/1	3/3	2/2	
4	9	6	3/3	3/3	3/3	2/2	2/2					1
5	5	4	1/1	1/1	1/1	1/1	1/1			1/1		1
6	3	1									1/1	
7	1	0										
Total	117	66	46/49	48/49	49/49	3/4	4/4	3/3	3/3	5/5	3/3	2
Mean Age:	1.9 Years		(93.9%)	(98.0%)	(100%)							

Overall Conversion Rates

Measles	Mumps	Rubella
49/53	56/57	59/59
(92.5%)	(98.2%)	(100%)

Table 2

Serological Findings Among Children Who Received a 1.0 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:					Initially Seropositive to:	
			Measles-Mumps-Rubella			Measles-Rubella		Mumps Only	Measles Mumps and Rubella
			Conversions/Total			Conversions/Total			
Measles	Mumps	Rubella	Measles	Rubella					
(Months) 11	1	1	1/1	1/1	1/1				
(Years) 1	11	8	7/7	7/7	7/7			1/1	
2	5	2				1/1	1/1	1/1	
3	1	0							
5	2	1	1/1	1/1	1/1				
Total	20	12	9/9	9/9	9/9	1/1	1/1	2/2	0
Mean Age:	1.7 Years		(100%)	(100%)	(100%)				

Overall Conversion Rates

Measles	Mumps	Rubella
10/10	11/11	10/10
(100%)	(100%)	(100%)

8/24/77

Table 3

Serological Findings Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (HPV-77) Virus Vaccine, M-M-R (Study 6467)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:									Initially Seropositive to: Measles Mumps and Rubella	
			Measles-Mumps-Rubella			Measles-Rubella		Mumps-Rubella		Measles Only	Mumps Only		
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/Total	Conversions/Total		
			Measles	Mumps	Rubella	Measles	Rubella	Mumps	Rubella	Total	Total		
(Months)													
10	1	0											
11	2	2	1/2	1/2	2/2								
(Years)													
1	88	46	36/42	36/42	40/42	3/3	3/3				1/1		
2	19	10	3/3	2/3	3/3	2/2	2/2	1/1	1/1	1/1	2/2	1	
3	12	6	4/4	4/4	3/4	1/1	1/1	1/1	1/1				
4	12	3	1/1	1/1	0/1	2/2	2/2						
5	3	2	1/1	1/1	1/1	1/1	1/1						
7	1	1										1	
Total	138	70	46/53	45/53	49/53	9/9	9/9	2/2	2/2	1/1	3/3	2	
Mean Age:	1.7 Years		(86.8%)	(84.9%)	(92.5%)								

Overall Conversion Rates

Measles	Mumps	Rubella
56/63 (88.9%)	50/58 (86.2%)	60/64 (93.8%)

8/24/77

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella, Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Measles (HAI)		Mumps (Neut.)		Rubella (HAI)	
Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children
<5	3	<2	1	16	1
5	2	2	8	32	1
10	2	4	11	64	11
20	4	8	8	128	22
40	9	>8	1	256	10
80	8	16	10	512	4
160	17	32	7		
320	4	64	3		
Total	49		49		49
Geometric Mean Titer	56.2		8.3		131.7

8/24/77

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella, Who Received a 1.0 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/G-D763 (Study #467)

Measles (HAI)		Mumps (Neut.)		Rubella (HAI)	
Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children
160	4	2	2	64	1
320	4	4	5	128	2
640	1	8	1	256	3
		16	1	512	2
				1024	1
Total	9		9		9
Geometric Mean Titer	254.0		4.3		256.0

8/24/77

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella, Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (MPV-77) Virus Vaccine, M-M-R (Study #467)

Measles (HAI)		Mumps (Neut.)		Rubella (HAI)	
Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children	Post Titer Distribution	Number of Children
<5	7	<2	8	<8	4
5	2	2	9	8	9
20	2	4	14	16	7
40	6	8	9	32	11
80	14	>8	1	64	7
160	17	16	6	128	9
320	4	32	4	256	4
640	1	64	2	512	1
				1024	1
Total	53		53		53
Geometric Mean Titer	51.1		5.0		32.4

8/24/77

Table 7

Maximum Temperatures Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Maximum Temperature (°F, Oral)	Total Vaccines (117 Children)					No. with Max. Temp.	Initially Seronegatives (61 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	61 (73.5%)	53 (64.6)	61 (75.3)	59 (73.8)	57 (72.2)	39	34 (77.3)	29 (69.0)	34 (79.1)	34 (81.0)	32 (78.0)	25
99 - 100.9	20 (24.1)	23 (28.0)	17 (21.0)	16 (20.0)	16 (20.3)	26	10 (22.7)	8 (19.0)	7 (16.3)	7 (16.7)	8 (19.5)	12
101 - 102.9	1 (1.2)	5 (6.1)	2 (2.5)	3 (3.8)	4 (5.1)	13		4 (9.5)	1 (2.3)	1 (2.4)		5
103 - 104.0	1 (1.2)	1 (1.2)	1 (1.2)	2 (2.5)	2 (2.5)	7		1 (2.4)	1 (2.3)		1 (2.4)	3
Not Taken	34	35	36	37	38	32	17	19	18	19	20	16

8/24/77

Table 8

High Temperatures Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Patient No.	Max. Temp.	Time Period (Days)	Clinical Complaints	Serology					
				Measles		Mumps		Rubella	
				Pre	Post	Pre	Post	Pre	Post
(b) (8)	102.0	29-31	Upper Respiratory Illness	NS	NS	NS	NS	NS	NS
	102.0	3	Anorexia	NS	NS	NS	NS	NS	NS
	102.0	24-28	Upper Respiratory Illness, Gastrointestinal Illness, Irritability						
	102.0	27	No Clinical Complaints	NS	NS	NS	NS	NS	NS
	103.0	26-29	Anorexia, Teething	NS	NS	NS	NS	NS	NS
	103.0	0-3	Upper Respiratory Illness	NS	NS	NS	NS	NS	NS
	103.2	9-11	Upper Respiratory Illness, Otitis, Lymphadenopathy, Ophthalmopathy, Gastrointestinal Illness, Anorexia, Soreness at Injection Site	<5	160	<2	32	<8	512
	104.0	22-23	Upper Respiratory Illness, Gastrointestinal Illness, Headache	>20	40	2	4	>32	128
	103.6	40-41	Upper Respiratory Illness, Headache Anorexia	>20	80	<2	16	>32	128
	102.0	7-8	No Clinical Complaints	<5	80	<2	4	<8	128
	102.0	12	Upper Respiratory Illness, Ophthalmopathy	<5	<5	<2	8	<8	128
	103.0	30-33	Upper Respiratory Illness, Gastrointestinal Illness	<5	10	<2	2	<8	128
	103.0	18	Upper Respiratory Illness, Teething	<5	5	<2	32	<8	256
	102.0	10-12	No Clinical Complaints	<5	40	<2	32	<8	256

8/24/77

Table 9

Maximum Temperatures Reported Among Children Who Received a 1.0 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Maximum Temperature (°F, Oral)	Total Vaccinees (20 Children)						Initially Seronegatives (11 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	13 (76.5%)	11 (64.7)	13 (81.3)	12 (70.6)	13 (76.5)	9	7 (70.0)	7 (70.0)	8 (80.0)	6 (60.0)	7 (70.0)	6
99 - 100.9	3 (17.6)	4 (23.5)	2 (12.5)	4 (23.5)	3 (17.6)	5	3 (30.0)	2 (20.0)	1 (10.0)	3 (30.0)	2 (20.0)	3
101.0		2 (11.8)			1 (5.9)	1		1 (10.0)			1 (10.0)	0
103.0	1 (5.9)		1 (6.3)	1 (5.9)		2			1 (10.0)	1 (10.0)		1
Not Taken	3	3	4	3	3	3	1	1	1	1	1	1

Patient No.	Max. Temp.	Time Period (Days)	Clinical Complaint	Measles	Mumps	Rubella
(b) (5)	103.0	0	No Clinical Complaint	NS	NS	NS
	103.0	13-15	No Clinical Complaint	<S	160	<2 4
	103.0	22	No Clinical Complaint			<8 256

8/24/77

Table 10

Maximum Temperatures Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (MPV-77) Virus Vaccine, M-M-R (Study #467)

Maximum Temperature (°F., Oral)	Total Vaccines (138 Children)					No. with Max. Temp.	Initially Seronegatives (70 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	73 (74.5%)	66 (68.0)	78 (81.3)	75 (78.1)	73 (78.5)	53	38 (76.0)	35 (70.0)	43 (86.0)	40 (80.0)	39 (81.3)	29
99 - 100.9	22 (22.4)	24 (24.7)	15 (15.6)	16 (16.7)	14 (15.1)	27	10 (20.0)	9 (18.0)	5 (10.0)	8 (16.0)	4 (8.3)	10
101 - 102.9	3 (3.1)	4 (4.1)	2 (2.1)	2 (2.1)	5 (5.4)	14	2 (4.0)	3 (6.0)	1 (2.0)		4 (8.3)	8
103 - 104.9		3 (3.1)	1 (1.0)	3 (3.1)	1 (1.1)	6		3 (6.0)	1 (2.0)	2 (4.0)	1 (2.1)	5
Not Taken	60	41	42	42	45	38	20	20	20	20	22	18

Patient No.	Max. Temp.	Time Period (Days)	Clinical Complaint	Measles	Mumps	Rubella			
(b) (6)	102.0	5-6	Otitis	<5	320	<2	4	<8	16
	104.0	19-23	Upper Respiratory Illness, Nonspecific Viral Rash, Anorexia	<5	320	2	8	8	64
	103.0	34-39	Teething	<5	<5	<2	32	<8	1024
	103.0	8-10	No Clinical Complaints	<5	320	<2	8	<8	<8
	104.0	28	No Clinical Complaints						
	103.2	13-14	No Clinical Complaints	<5	640	<2	8	<8	256
	103.2	25	No Clinical Complaints						
	102.0	4-5	No Clinical Complaints	qns	80	qns	4	qns	64
	102.0	27-36	Gastrointestinal Illness, Nonspecific Rash, Anorexia	<5	40	<2	28	<8	32
	102.0	5-10	Upper Respiratory Illness, Anorexia	<5	160	<2	<2	<8	128
	102.0	15	Upper Respiratory Illness, Otitis	NS	NS	NS	NS	NS	NS
	102.0	30-34	Upper Respiratory Illness	<5	40	<2	<2	<8	8
	102.4	1	No Clinical Complaints	<5	160	<2	32	<8	128
	103.0	7-12	Gastrointestinal Illness, Irritability, Anorexia, Teething	<5	160	<2	32	<8	32
	103.0	8-10	Ophthalmopathy	<5	160	<2	2	<8	32

Table 11

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-8763 (Study #467)

Clinical Complaint	Total Vaccinees (117 Children)					No. with Complaint	Initially Seronegatives (61 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-62		0-4	5-12	13-18	19-28	29-62	
Soreness at Injection Site	2 (2.2)	1 (1.1)	1 (1.1)			3	1 (2.1)	1 (2.1)	1 (2.1)			2
Lymphadenopathy		2 (2.2)		1 (1.1)		3		2 (4.3)		1 (2.1)		3
Measles-Like Rash	1 (1.1)	5 (5.6)	3 (3.4)			7	1 (2.1)	4 (8.5)	1 (2.1)			5
Headache		1 (1.1)		1 (1.1)	1 (1.1)	3		1 (2.1)				1
Irritability	4 (4.4)	4 (4.5)		1 (1.1)		8	3 (6.3)	1 (2.1)				4
Fever-Temperature Not Reported	1 (1.1)	1 (1.1)				2		1 (2.1)				1
Anorexia	10 (11.1)	12 (13.5)	6 (6.7)	7 (8.0)	6 (6.8)	23	5 (10.4)	7 (14.9)	4 (8.3)	2 (4.3)	1 (2.1)	11
Flush					1 (1.1)	1						0
Disturbed Sleep	2 (2.2)					2						0
Hyalgia	1 (1.1)					1	1 (2.1)					1
Upper Respiratory Illness	15 (16.7)	29 (32.6)	17 (19.1)	20 (22.7)	31 (35.2)	53	6 (12.5)	13 (27.7)	9 (18.8)	9 (19.1)	10 (21.3)	22
Otitis	1 (1.1)	2 (2.2)	2 (2.2)	1 (1.1)	1 (1.1)	2		1 (2.1)	1 (2.1)			1
Ophthalmopathy		5 (5.6)	4 (4.5)	3 (3.4)	4 (4.5)	9		3 (6.4)	3 (6.3)	2 (4.3)	1 (2.1)	4
Gastrointestinal Illness	9 (10.0)	15 (16.9)	10 (11.2)	12 (13.6)	13 (14.8)	31	4 (8.3)	12 (25.5)	6 (12.5)	7 (14.9)	4 (8.5)	16
Nonspecific Rash	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	4 (4.5)	6		1 (2.1)				1
Poison Ivy		1 (1.1)	1 (1.1)			1						0
Allergy		1 (1.1)		1 (1.1)		2		1 (2.1)		1 (2.1)		2
Teething	1 (1.1)	4 (6.5)	4 (6.5)	2 (2.3)	2 (2.3)	10	1 (2.1)	2 (4.3)	2 (4.2)			5
Negative Surveillance	27	28	28	29	29	27	11	14	13	14	14	13
Persons with Complaint:	30 (33.3)	44 (49.4)	28 (31.5)	30 (34.1)	37 (42.0)	56	12 (25.0)	21 (46.7)	16 (29.2)	14 (29.8)	13 (27.7)	25
Persons with No Complaint:	60 (66.7)	65 (50.6)	61 (68.5)	58 (65.9)	51 (58.0)	33	36 (75.0)	26 (55.3)	34 (70.8)	33 (70.2)	34 (72.3)	23

Table 12

Clinical Complaints Reported Among Children Who Received a 1.0 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Clinical Complaint	Total Vaccinees (20 Children)					No. with Complaint	Initially Seronegatives (11 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Soreness at Injection Site	1 (5.9%)					1	1 (10.0)					1
Lymphadenopathy	1 (5.9)					1	1 (10.0)					1
Arthralgia			1 (5.9)			1						0
Measles-Like Rash			1 (5.9)			1			1 (10.0)			1
Irritability	1 (5.9)	1 (5.9)				1	1 (10.0)	1 (10.0)				1
Fever - Temperature Not Reported				1 (5.9)		1				1 (10.0)		1
Anorexia			1 (5.9)	1 (5.9)		2			1 (10.0)			1
Upper Respiratory Illness	4 (23.5)	5 (29.4)	2 (11.8)	4 (23.5)	1 (5.9)	8	1 (10.0)	1 (10.0)		2 (20.0)		4
Otitis			1 (5.9)	1 (5.9)	1 (5.9)	1			1 (10.0)	1 (10.0)	1 (10.0)	1
Gastrointestinal Illness	3 (17.6)		1 (5.9)	1 (5.9)		4	2 (20.0)		1 (10.0)			2
Impetigo				1 (5.9)		1				1 (10.0)		1
Negative Surveillance	3	3	3	3	3	3	1	1	1	1	1	1
Persons with Complaint:	7 (41.2)	6 (35.3)	5 (29.4)	5 (29.4)	2 (11.8)	9	3 (30.0)	2 (20.0)	2 (20.0)	3 (30.0)	1 (10.0)	5
Persons with No Complaint:	10 (58.8)	11 (64.7)	12 (70.6)	12 (70.6)	15 (88.2)	8	7 (70.0)	8 (80.0)	8 (80.0)	7 (70.0)	9 (90.0)	5

Table 13

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (MMV-77) Virus Vaccine, M-M-R (Study #467)

Clinical Complaint	Total Vaccinees (138 Children)					No. with Complaint	Initially Seronegatives (70 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Sites:	7 (6.9%)					7	3 (5.7)					3
Soreness	6					6	2					2
Soreness and Induration	1					1	1					1
Systemic:												
Measles-like Rash		5 (5.0)	2 (2.0)			5		1 (1.9)				1
Headache	1 (1.0)		1 (1.0)		2 (2.0)	2					1 (1.9)	1
Irritability	3 (3.0)	4 (4.0)	2 (2.0)	3 (3.0)		9	2 (3.8)	1 (1.9)		1 (1.9)		4
Anorexia	11 (10.9)	17 (16.8)	5 (5.0)	6 (5.9)	4 (4.0)	24	6 (11.3)	9 (17.0)	1 (1.9)	3 (5.7)	3 (5.7)	14
Flush	1 (1.0)					1						0
Disturbed Sleep		1 (1.0)				1						0
Hyalgia	2 (2.0)					2	1 (1.9)					1
Upper Respiratory Illness	18 (17.8)	19 (18.8)	15 (14.9)	18 (17.8)	24 (23.8)	65	10 (18.9)	9 (17.0)	6 (11.3)	7 (13.2)	8 (15.1)	20
Otitis	1 (1.0)	4 (4.0)	2 (2.0)	1 (1.0)	1 (1.0)	7	1 (1.9)	2 (3.8)				3
Ophthalmopathy	2 (2.0)	3 (3.0)		1 (1.0)	2 (2.0)	6	2 (3.8)	2 (3.8)				4
Gastrointestinal Illness	15 (14.9)	12 (11.9)	5 (5.0)	5 (5.0)	6 (5.9)	27	7 (13.2)	3 (5.7)	3 (5.7)	2 (3.8)	4 (7.5)	11
Rash-Non-specific	1 (1.0)	3 (3.0)	5 (5.0)	3 (3.0)	4 (4.0)	12	1 (1.9)	1 (1.9)	4 (7.5)	1 (1.9)	1 (1.9)	6
Varicella				1 (1.0)	1 (1.0)	1						0
Other*	1 (1.0)	1 (1.0)				2	1 (1.9)					1
Genitourinary Infection				1 (1.0)	1 (1.0)	1						0
Allergy	2 (2.0)	2 (2.0)		1 (1.0)		3	2 (3.8)	2 (3.8)				2
Teething		2 (2.0)	4 (4.0)	5 (5.0)	2 (2.0)	8		1 (1.9)		1 (1.9)	2 (3.8)	3
Negative Surveillance	37	37	37	37	37	37	17	17	17	17	17	17
Persons with Complaint:	36 (27.6)	41 (40.6)	24 (23.8)	26 (25.7)	30 (29.7)	57	20 (37.7)	18 (34.0)	9 (17.0)	10 (18.9)	12 (22.6)	27
Persons with No Complaints	65 (64.4)	60 (59.4)	77 (76.2)	75 (74.3)	71 (70.3)	44	33 (62.3)	35 (66.0)	44 (83.0)	43 (81.1)	41 (77.4)	26

* Includes ingested lighter fluid and bloody nose.

MEMO

To File Location Date 9/27/77
From T. Schofield Location W26-285
Subject Statistical Analysis - Study #467

Significant differences in seroconversion rates for measles, mumps, and rubella and clinical reaction rates among three groups of vaccinees were investigated. The groups were those who received a 0.5 ml dose of combined live measles-mumps-rubella (RA 27/3) virus vaccine (Group 1), those who received a 1.0 ml dose of the same (Group 2), and those who received a 0.5 ml dose of combined live measles-mumps-rubella (HPV-77) virus vaccine (Group 3).

Significant difference exists in the mumps seroconversion rate among these groups. 56 out of 57 (98.2%) converted in Group 1, 11 out of 11 (100.0%) in Group 2, and 50 out of 58 (86.2%) in Group 3. No significant differences exist for other rates.

Analysis of variance was performed on post-titer values of triple-negative vaccinees. The log transformation was used. Significant differences among the groups existed for all three components. Multiple comparisons showed the following:

- a) For measles, children in Group 2 (GMT = 254.0) had significantly greater post titer (in the log scale) than did those in Group 1 (GMT = 56.2) and those in Group 3 (GMT = 51.1);
- b) For mumps, children in Group 1 (GMT = 8.3) had significantly greater post titer than did those in Group 2 (GMT = 4.3) and those in Group 3 (GMT = 5.0);
- c) For rubella, children in Group 1 (GMT = 131.7) and Group 2 (GMT = 256.0) had significantly greater post titer than did those in Group 3 (GMT = 32.4).



T.S.
6801



CLINICAL SUMMARY

Study Name - Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Study Number - Clinical Protocol -467

Material - Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #621/C-D763

Combined live measles-mumps-rubella (HPV-77) virus vaccine
Lot #0131V

Purpose - To compare clinical and antibody responses to combined live measles-mumps-rubella virus vaccine containing the RA 27/3 rubella virus strain or the HPV-77 duck rubella virus strain.

Time Period of
Observation - Initiated: June 7, 1976; completed: May 12, 1977

Medical Opinion

At the following locations: Burlington County Health Care Clinics-Riverside Clinic, Zurbrugg Memorial Hospital, Riverside, New Jersey, Browns Mills Clinic, Deborah Hospital, Browns Mills, N.J., Mount Holly Clinic, Mt. Holly, N.J.; Delaware State Health Clinics, Dover Delaware and the DeLoWar Clinic and Northeast Clinic, Wilmington, Delaware; Elizabeth M. Craven, M.D., Pediatric Clinics, Wilmington Medical Center, Wilmington, Delaware; The Lankenau Hospital Pediatric Clinic, Philadelphia, Pa.; and George A. Starkweather, M.D.'s office, Havertown, Pa.; 275 children, 10 months to seven years of age were enrolled in this study with parental consent. Two-hundred fifty-five children received a 0.5 ml. subcutaneous dose of either vaccine. Inadvertently, twenty children received a 1.0 ml. subcutaneous dose of combined measles-mumps-rubella (RA 27/3) virus vaccine. Each child received a report card and the parents were encouraged to record local and systemic reactions for 42 days. Paired blood samples were obtained prior to and 6 weeks following vaccination from 148 of 275 (54%) children to perform measles hemagglutination inhibition, mumps neutralization and rubella hemagglutination inhibition tests.

Measles-mumps-rubella (RA 27/3) virus vaccine was given to 137 children, ages 11 months to 7 years (mean age 1.9 years) with 78 paired sera, seropositive to m-m-r in two and seronegative as follows: m-m-r 58, measles-rubella 5, mumps-rubella 3, mumps 7, rubella 3 - 13 m-m-r seronegatives had only a pre-injection serology test. Measles-mumps-rubella (HPV-77) virus vaccine was given to 138 children, ages 10 months to seven years (mean age 1.7 years) with 70 paired sera seropositive to m-m-r in 2 and seronegative as follows: m-m-r 53, measles-rubella 9, mumps-rubella 2, measles 1, mumps 3 - 17 m-m-r seronegatives had only a pre-injection serology tested. Seroconversion rates for triple seronegatives were similar to the overall seroconversion rates which are as follows with the geometric mean titers: m-m-r (RA 27/3) vaccine 0.5 ml. dose; measles 49/53 (92.5%, 56.2); mumps 56/57 (98%, 8.3); rubella 59/59 (100%, 131.7); m-m-r RA 27/3 vaccine 1.0 dose; measles 10/10 (254); mumps 11/11 (4.37); rubella 10/10 all 100% (256); m-m-r HPV-77 vaccine 0.5 ml. dose; measles 56/63 (88.9%, 51.1); mumps 50/58 (86.2%, 50) rubella 60/64 (98.8%, 32.4).

Medical Opinion (cont.)

The seroconversion rates and geometric mean titers are greater following 0.5 ml. m-m-r RA 27/3 than 0.5 ml. m-m-r HPV as follows: measles - 92.5% vs. 88.8%, 56.2 vs. 51.1; mumps - 98.2% vs 86.2%, 8.3 vs. 5.0; rubella - 100% vs. 93.8%, 131.7 vs. 32.4. The difference in the mumps seroconversion rates, mumps geometric mean titers and rubella geometric mean titers are statistically significant. Interestingly, all (11) measles vaccine failures were less than 15 months of age (2-11, 6-12, 2-13, 1-14 months) and may be related to the persistence of maternal antibody. This pattern was not observed in previous studies. Two of 4 rubella failures (13 months) and 4 of 8 mumps failures were less than 15 months old (1-11, 2-12, 1-13 months).

Clinical report cards were returned on 202 of 275 (73%) of vaccinees with no significant vaccine related clinical reaction reported. Temperature elevations were similar among both vaccine groups with no definite pattern during the observation period. Most temperature elevations are related to intercurrent infection with minimal vaccine related fever occurring between days 5 and 12. Injection site soreness was rarely reported in each group. Measles-like rash was reported in m-m-r RA 27/3 vaccinees as follows: 0.5 ml. - 7, 1.0 ml. - 1, and in 5 m-m-r HPV vaccinees. No arthralgia or arthritis were reported. Lymphadenopathy was reported by 4 m-m-r RA 27/3 vaccinees only. Non-specific complaints were similar in both groups.

Comparing combined m-m-r RA 27/3 vaccine with m-m-r HPV-77 vaccine reveals no difference in the mild clinical complaints and temperature elevations reported but a greater seroconversion rate and geometric mean titer to all three viruses following m-m-r RA 27/3 vaccine. Although both vaccines are excellent for immunization, m-m-r RA 27/3 combined vaccine is superior and recommended.



Robert E. Weibel, M.D.
October 5, 1977

REW:ceb

Reference No. 5

Clinical Protocol - Study #473Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Program: Testing of combined live measles-mumps-rubella vaccines in children.

Purpose: To evaluate and compare clinical and immunological responses to two measles-mumps-rubella virus vaccines.

Vaccines: 1. Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #621/C-D763

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

2. Combined live measles-mumps-rubella (HPV-77 duck) virus vaccine
Lot #2127V or 2209V

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial of vaccine should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: Both vaccines may contain egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. The vaccines also contain neomycin and should not be given to persons with sensitivity to neomycin. Persons with leukemia or other immunologic disorders and persons receiving immunosuppressive drugs should not be vaccinated. The vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccine stored at -20° C.

Keep dried vaccines at 4° C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of children 1 to 10 years of age who have a negative history of vaccination for and illness caused by measles, mumps and rubella. The children will be assigned to receive one of the two vaccine as follows:

Clinical Protocol - Study #473
 Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

<u>Procedure:</u> (continued)	<u>Group</u>	<u>Vaccine</u>	<u>No. of Persons</u>
	1	M-M-R (HPV-77 + 5 duck)	up to 200 children
	2	M-M-R (RA 27/3)	up to 200 children

Informed written consent will be obtained from a parent or guardian of each child prior to his participation in the study.

Each child will be bled (10-15 ml) immediately prior to vaccination and 6-8 weeks following vaccination. Each child will receive 0.5 ml of vaccine given subcutaneously.

Each child will be followed clinically for occurrence of local and systemic reactions within 6 weeks following vaccination. Observations should include special notation for rash, nodes, arthralgia, arthritis, fever, malaise, and anorexia. The person(s) observing reactions should not know which preparation the child received.

Schedule:

Time	Action
Day 0	Bleed 10-15 ml. Vaccinate 0.5 ml, subcutaneously.
Days 0-42	Clinical follow-up for local and systemic reactions.
Weeks 6-8	Bleed 10-15 ml.

Laboratory: Remove serum from clot aseptically and store frozen at -20° C.

Serology: Levels of circulating antibody before and after vaccination will be determined. Measles and rubella antibody levels will be determined by hemagglutination-inhibition test. Mumps antibody levels will be determined by serum neutralization test.

Clinical
 Forms: Attached.

Adverse
 Reactions: Any serious or alarming reaction, including death due to any cause during this investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Arlene McLean, telephone (215) 699-5311, Ext. 6383.

Clinical Protocol - Study #473
Combined Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Unused
Vaccine:

All unused vaccine should be returned immediately to the Virus and Cell Biology Laboratories of the Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.



M. R. Hilleman, Ph.D.

Yale University *New Haven, Connecticut 06510*

SCHOOL OF MEDICINE
*Department of Epidemiology
and Public Health
60 College Street*

October 12, 1977

Dr. Arlene McClaine
Merck Institute For Therapeutic
Research
West Point, Pennsylvania

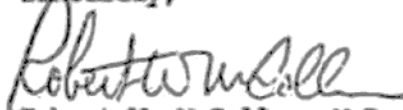
Dear Doctor McClaine:

As a follow-up to our recent telephone conversation, I submit the following information about our current participation in studies concerned with comparisons of HPV-77 DE_c and RA27/3 live attenuated rubella virus vaccines (b) (4), (b) (6). Our studies in children have now been approved at all levels in each of the various pediatric clinic settings, but have not yet been started. After several prolonged difficulties in filling the position of central coordinator, we now have a good person whose interest, capabilities and prior record give both Dr. Horstmann and me a feeling of reassurance about essential features of recruitment and follow-up of eligible participants. We anticipate a vast improvement in the studies, both qualitative and quantitative.

To date (b) (4), (b) (6)
(b) (4), (b) (6)

I will send you a progress report on the (b) (4), (b) (6) after our new organizational effort has begun to bear fruit.

Sincerely,


Robert W. McCollum, M.D.
Chairman

BWM/fn

SYMPTOM RECORD

M-M-R STUDY NO. _____

NAME (Last) _____ (First) _____ (Middle) _____ CASE NO. _____

DAY	DATE	Temperature		NONE	RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	VOMITING	DIARRHEA	NAUSEA	* RASH	SORE JOINTS	* SORE ARM (at shot)	HEADACHE	ACHINESS	FEVER	LOSS OF APPETITE	*Describe	COMMENTS	
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral (Check One)																				
0																							
1																							
2																							
3																							
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ever or unusual reaction develops, call:

PLEASE RETURN FOR FOLLOW-UP VISIT ON: _____

BE SURE TO BRING THIS RECORD ALONG WITH YOU.

INSTRUCTIONS:

1. Please fill in the date each day.
2. Please take temperature once daily at the same time and record exact thermometer reading.
3. If no symptoms are present, place a check (✓) under "NONE" beside that day's date.
4. If a symptom is present, place a check (✓) under it beside that day's date.
5. Describe other symptoms and any RASH in the space under "COMMENTS."
6. THIS IS VERY IMPORTANT INFORMATION. *Please do not misplace this card.*

MEASLES - MUMPS - RUBELLA

Study No. (1-3)

Case No. (3-9)

CT 2	Name	Sex (3)	Birthdate (2-4)	(46-47)
		M F	mo day yr	
Address				
Indicate if this child:				
<input type="checkbox"/> had disease		Did child develop clinical disease. 1 = YES 2 = NO		
<input type="checkbox"/> been vaccinated		Date of onset: _____		
<input type="checkbox"/> been exposed		Comments: _____		
Date of exposure: _____		Diagnosed by: _____		
<input type="checkbox"/> Vaccine <input type="checkbox"/> Control		Date of Vaccination		Bleeding Dates: _____ (58-62)
Lot No. (48-52)		(52-57)		(70-75)

CT 3	DAY	DATE	Temperature		Malaise	Anorexia	Gastrointestinal	Irritability	Headache	Upper Respiratory	Erythema	Conjunctivitis	Lymphadenopathy	Local Reaction*	Rash*				Arthralgia	Arthritis	*Specify (Type, Location)				
			Oral	Rectal											51	52	11	32				OTHER REACTIONS			
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Please return completed forms to: *Return PINK copy for your files!*

Dr. R. HILLEMAN, PhD, DSc
 MERCK SHARP & DOHME RESEARCH LABORATORIES
 WEST POINT, PENNSYLVANIA, 19406, U.S.A.

Physician's Signature _____
 Physician's Name (Type or Print) _____
 Date _____

Reference No. 6

Program: Study #484 - To evaluate and compare clinical and immunological responses to two combined live measles-mumps-rubella virus vaccines.

Vaccine: Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot #621/C-D763

Combined live measles-mumps-rubella (HPV-77) virus vaccine
M-N-R

Responsible Clinical Investigator:

Anne Garshon, M.D.
8th Floor North 16
Bellevue Hospital
1st Avenue and East 27th Street
New York, New York 10016

Study Location: New York, New York

Date Study Initiated: December 23, 1976

Date Study Completed: In Progress

Study Procedure:

Sixty-three children, 13 months to 15 years of age, and one adult, have been included in the study thus far. Thirty received a 0.5 ml subcutaneous dose of one of the two vaccines. Thirty-four children received a 1.0 ml subcutaneous dose of combined live measles-mumps-rubella (RA 27/3) virus vaccine. Blood samples were obtained on day of vaccination and 8-12 weeks after vaccination. Each child was followed 6 weeks for clinical complaints. The study continues in progress.



NEW YORK UNIVERSITY MEDICAL CENTER

School of Medicine

550 FIRST AVENUE, NEW YORK, N.Y. 10016

AREA 212 679-3200

CABLE ADDRESS: NYUMEDIC

Department of Pediatrics

December 19, 1977

Arlene McLean, Ph.D.
Merck Sharp & Dohme
Research Laboratories
West Point, PA
19486

Dear Arlene,

Enclosed is a follow-up on the progress report I sent you in August. I have simply updated the tables because they really tell the whole story. If you want anything more detailed than this, please let me know.

With best regards.

Sincerely yours,

Anne A. Gershon, M.D.
Associate Professor
Dept. of Pediatrics

AAG/mac
Enclosure

MMR Study: Children 1-15 years old

12/19/77

	RA 27/3	HPV 77
<u>Number vaccinated</u>	<u>39</u>	<u>25</u>
Number vaccinated with follow-up serum specimens	13	7
Number susceptible	13/13	7/7
Number with seroconversion	13/13	7/7
Number with reaction	0/13	0/7
Reactions (none)		



NEW YORK UNIVERSITY MEDICAL CENTER

School of Medicine

150 FIRST AVENUE, NEW YORK, N.Y. 10016

AREA 212 679-1200

CABLE ADDRESS NYUMEDIC

Department of Pediatrics

August 17, 1977

Maurice R. Hilleman, Ph.D.
Director
Virus & Cell Biology Research
Merck Sharp & Dohme
West Point, Pennsylvania 19486

Dear Dr. Hilleman,

I am enclosing a progress report on our study of rubella vaccines RA 27/3 vs HPV 77, in adults and children. We are continuing to immunize and more data should be forthcoming.

With best regards.

Sincerely yours,

Anne A. Gershon, M.D.
Associate Professor
Dept. of Pediatrics

AAG/mac
Enclosure

cc: Dr. Arlene McLean ✓

2. Infants and children were given rubella RA 27/3 or HPV 77 in combination with their regular measles and mumps vaccine (MMR). The ages of the subjects ranged from 13 months to 15 years. Informed parental consent was obtained. At the time of MMR immunization a blood sample was obtained to determine the child's immune status with regard to rubella. A second blood sample was obtained approximately 8-12 weeks after MMR immunization for rubella HI titer.

The subjects who received HPV 77 rubella vaccine in MMR received the standard dose of vaccine. Those who received RA 27/3 rubella vaccine in MMR received double the usual dose of vaccine. All vaccines were given by subcutaneous injection.

Thirty four children received RA 27/3 rubella vaccine as MMR. There has been follow-up on 5 of these subjects so far. All have developed rubella HI antibody with a titer of 1:128 or 1:256. No reactions to the vaccine have been reported. Follow-up on more of these vaccine recipients will be obtained with time.

Seventeen children and 1 adult received HPV 77 rubella vaccine as MMR. To date follow-up has been obtained on 3 of these children; additional follow-ups are expected to be forthcoming. Of the 3 who have been followed, one had an initial rubella HI titer of ≥ 32 at immunization and an HA

titer of 1:128 after vaccination. Two children had titers which were <1:8 at vaccination and increased to 1:16 and 1:32 after vaccination.

School of Medicine
550 FIRST AVENUE, NEW YORK, N.Y. 10016
AREA 212 679-3200
CABLE ADDRESS: NYUMEDIC

Department of Pediatrics

October 3, 1977

Dr. Arlene McClean
Merck Sharp and Dohme
Research Laboratories
West Point, Pennsylvania 19486

Dear Dr. McClean,

Please find enclosed an information sheet given to the mothers of children receiving the M-M-R vaccine. They are asked to record any reactions to the vaccine and return the slip to the doctor in the Pediatric Clinic. This information is given to Dr. Judy Wallin, who is supervising the study in the Pediatric Clinic at Bellevue Hospital. She keeps this information and we are informed via "word of mouth" with regard to these reactions.

I apologize for the confusion.

Thank you.

Sincerely yours,



Maura Caruth
Secretary to Dr. Anne Gershon
Dept. of Pediatrics

Baby's Name _____ Date of Vaccination _____

Your baby has just received a measles-mumps-rubella vaccination. He/she will probably have no symptoms afterward. If you think the baby is having a reaction, please take the baby's temperature. Write down any problems the baby is having:

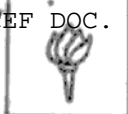
	<u>YES</u>	<u>NO</u>
Fever		
Rash		
Joint pain		
Swelling Where?		

If the baby seems sick please telephone Dr. Gershon or Dr. Reese at 561-3612 between 9 AM-5 PM. If the baby is sick on a weekend or at night take him/her to the PES. They will contact a doctor for you.

These vaccines are safe and an important part of your baby's health care to prevent disease.

We will contact you in 2 months by telephone or letter about drawing a second blood sample from your baby. There will be no charge for the second blood drawing. It will tell you whether your baby is immune to measles and German measles (rubella) because of the vaccination.

PLEASE SAVE THIS LETTER AND BRING IT BACK TO CLINIC WITH YOU



NEW YORK UNIVERSITY MEDICAL CENTER

School of Medicine

350 FIRST AVENUE, NEW YORK, N.Y. 10016

AREA 212 679-3200

CABLE ADDRESS NYUMEDIC

Department of Pediatrics

September 21, 1976

Arlene A. McLean, Ph.D.
Merck Sharp & Dohme
Research Laboratories
Division of Merck & Co., Inc.
West Point, Pennsylvania 19486

Dear Dr. McLean:

Enclosed is a copy of the revised consent form for measles-mumps-rubella RA 27/3 vaccine, and a letter from the Chairman of the Human Use Committee granting approval of the consent.

I hope we can have the new vaccine soon.

Many thanks.

Sincerely yours,

Anne A. Gershon, M.D.
Associate Professor
Department of Pediatrics

AAG:rr
Enclosure

NEW YORK UNIVERSITY MEDICAL CENTER

School of Medicine

530 FIRST AVENUE, NEW YORK, N.Y. 10016

Tel: 212-679-1199

FAX: 212-679-1199

Department of Pediatrics

STUDY OF MEASLES - MUMPS - RUBELLA VACCINE

In the United States, measles, mumps and rubella (German measles) vaccine should be given to babies between the ages of 12 months - 15 months. These vaccines are important because they provide babies and children with long-lasting immunity to measles, mumps and rubella (German measles).

Many clinics are now giving babies a combined measles-mumps-rubella vaccine in one injection. Our clinic has recently received a new vaccine which contains regular measles-mumps vaccine combined with a new, unlicensed rubella vaccine called RA-27. This RA-27 vaccine has been used experimentally in many children (in Europe) and it seems to produce better antibodies than the one which is now licensed for use in the United States.

Our study is designed to see how good this experimental rubella RA-27 vaccine really is. It is combined with the measles-mumps vaccine so that your child will only have to have one injection. We will also have to obtain a small sample of blood (5 ml or about a teaspoonful) before and eight weeks after the vaccine is given.

The known side effects of this type of vaccine are very few and occur only rarely in children. The side effects are fever, rash, and joint pain. Should any of these occur they will disappear after a few days without any treatment.

If you would like your child to receive the measles-mumps-RA-27-rubella vaccine you should sign this sheet in the space provided for your signature. Your child does not have to participate in this study if you do not want him (her) to. In that case your child should receive regular measles-mumps-rubella vaccine in our clinic. Should you decide to have your child participate in this study, his (her) participation will be kept strictly confidential.

SIGNATURE

WITNESS

DATE

NEW YORK UNIVERSITY MEDICAL CENTER

SYNOPSIS OF SPONSOR
PROGRAM ACTIVITIES

NAME OF P.I. OR PROJECT DIRECTOR Anne A. Gershon, M.D.		SOCIAL SECURITY NO. (b) (6)	DEPARTMENT Pediatrics	CODE
TITLE OF PROGRAM Measles - Rubella Vaccine Trial				
NAME OF SPONSOR			GRANT OR CONTRACT NO.	
TYPE OF PROGRAM: <input checked="" type="checkbox"/> RESEARCH, <input type="checkbox"/> EDUCATION & TRAINING, <input type="checkbox"/> FELLOWSHIP, <input type="checkbox"/> OTHER (EXPLAIN)			N.Y.U.M.C. #	

PART IVA HUMAN SUBJECTS (CONTINUED)

- A. List specific procedures to be used which involve human subjects or human materials; detail potential hazards and indicate the probability that they may occur. If procedure is heretofore untried, and hazards are not known, so indicate.
- B. Describe the benefit to the subject or advancement of knowledge that will balance the risk involved.
- C. Indicate measures proposed to minimize risk and, if applicable, methods for preserving confidentiality and rights of the subjects.

PROTOCOL

- A. 1. Venipuncture before and 8 weeks after vaccine is given. No appreciable hazard. 5 ml or less blood will be obtained.
2. Measles-rubella vaccine. No appreciable hazard. Measles component is a licensed product routinely given to infants of this age. Rubella vaccine is unlicensed in the United States, but has been widely given to children in Europe. Side effects from this vaccine are very few in children and similar in rate of occurrence to the rubella vaccine which is licensed in the United States. Possible side effects are rash, fever and joint pains all of which are transient. In a recent study conducted by Merck, the following side effects were observed. Those receiving licensed rubella vaccine: 24. rash - 0, arthralgia adenopathy - 0. Those receiving RA-27 rubella vaccine: 26. rash - 3, arthralgia - 1, adenopathy - 0.
- B. Benefit to patient - Infant will be immunized against rubella and measles with only one injection and one clinic visit. RA-27 rubella vaccine may provide better immunity than the presently licensed rubella vaccine.
- C. Sterile technique will be used at all times and the identity of the patient will not be revealed in any publications concerning this study.

MEASLES - RUBELLA VACCINATION

Study No. (1-3)

Case No. (2-3)

CT 2	Name	Sex (20) M F	Date of Birth (20-41) mo. day yr	(20-47)
Address				
History of this child: <input type="checkbox"/> had disease Did child develop clinical disease: 1 = YES 2 = NO <input type="checkbox"/> been vaccinated Date of onset: _____ <input type="checkbox"/> been exposed Comments: _____ Date of exposure _____ Diagnosed by: _____				
<input type="checkbox"/> Vaccine <input type="checkbox"/> Control Date of Vaccination _____ Blinding Code: _____ (20-62)				
Lot No. _____ (20-61) _____ (20-67) _____ (20-72)				

CT 2	DAY	DATE	Temperature		Malaise	Anorexia	Corticosteroid	Irritability	Headache	Upper Respiratory Infection	Orchitis	Conjunctivitis	Lymphadenopathy	Local Reaction*	Exanthema	Rash		Arthritis	Arteritis	*Specify (Type, Location) OTHER REACTIONS		
			Oral	Rectal												Rubella-like rash	Atypical					
			24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	
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Please return completed forms to: (Retain PINK copy for your files) M. R. HILLEMAR, PhD, DSc MERCK SHARP & DOHME RESEARCH LABORATORIES WEST POINT, PENNSYLVANIA, 19380, U.S.A.	Physician's Signature _____ Physician's Name (Type or Print) _____	Date _____
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Reference No. 7

Program: Study #511 - To measure antibody and clinical responses to three consecutive lots of combined measles-mumps-rubella virus vaccine.

Vaccines: Combined live measles-mumps-rubella (RA 27/3) virus vaccine, lyophilized

Lot #60664/C-E810

Lot #60665/C-E811

Lot #60666/C-E812

Responsible Clinical Investigator:

Victor M. Villarejos, M.D.
Director
Louisiana State University
International Center for Medical
Research and Training
Apartado 10.155
San Jose, Costa Rica

Study Location: Nicaragua

Date Study Initiated: July 4, 1977

Date Study Completed: September 14, 1977

Study Procedure:

One hundred fifty children, 8 months to 11 years of age, were included in the study. Each received a 0.5 ml subcutaneous dose of combined live measles-mumps-rubella virus vaccine. Blood samples were obtained on day of vaccination and 6 weeks after vaccination. Each child was followed 6 weeks for clinical complaints.

Clinical Protocol - Study #511Combined Live Measles-Mumps-Rubella (RA 27/3)Virus Vaccine

Program: Combined live measles-mumps-rubella virus vaccine

Purpose: To measure antibody and clinical responses to three consecutive lots of vaccine.

Vaccine: Combined live measles-mumps-rubella virus vaccine, lyophilized,
Lot. No. 60664/C-E810
Lot. No. 60665/C-E811
Lot. No. 60666/C-E812

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water which is supplied in prefilled syringes.

CAUTION: The vaccine contains egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. The vaccine contains neomycin and should not be given to persons sensitive to neomycin. Persons with leukemia or other immunologic disorder and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccine should not be given to persons with a febrile respiratory illness or other active febrile infection.

Keep dried vaccine stored at -20° C until used.

Keep dried vaccine at 4° C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of up to 150 children with a negative history for vaccination and illness caused by measles, mumps and rubella viruses. The children should range from 1 to 6 years of age.

Approximately 25 to 50 children will receive each of the three vaccine lots.

Informed written consent will be obtained from a parent or guardian of each child who participates in the study.

Clinical Protocol - Study #511
 Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Procedure:
 (Continued)

Each child will receive a 0.5 ml subcutaneous injection of vaccine.

Bleeding samples (10-15 ml) will be obtained from each child immediately before and 6 weeks after vaccination.

Each child will be followed clinically for local and systemic complaints occurring within 6 weeks after vaccination. Observations should include special notation for rash, nodes, arthralgia, arthritis, fever, malaise and anorexia. All complaints should be recorded on the case report form.

Schedule:

Time	Action - All Persons
Day 0	Bleed 10-15 ml Vaccinate 0.5 ml, subcutaneously
Days 0-42	Clinical follow-up for local and systemic complaints
Week 6	Bleed 10-15 ml

Laboratory:

Remove serum from clot aseptically and store frozen at -20° C until shipped. It is imperative that sera are sterile to avoid interference with the serologic assay.

Serology:

Levels of circulating measles and rubella antibodies will be determined by hemagglutination-inhibition test. Levels of mumps antibody before and after vaccination will be determined by serum neutralization test.

Clinical Forms: Attached.

Adverse

Reactions:

Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Arlene A. McLean, telephone (215) 699-5311, Ext. 6383.

Clinical Protocol - Study #511
Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.

Shipping of

- Sera & Records:
1. Send sera frozen within insulated containers which are supplied.
 2. Send sera and records to Dr. Maurice R. Hilleman, Virus & Cell Biology Research, Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.
 3. Alert Dr. Hilleman by cable as soon as possible regarding flight number, air bill and date of arrival.



M. R. Hilleman, Ph.D.

CT 2 Nombre completo del niño: _____
 Fecha de nacimiento (35-41) _____
 día mes año

Dirección completa de Padres o Guardián: _____
 VACUNADO NO. de LOTE _____ (49-51) FECHAS de SANGRIA _____ SEROLOGIA _____
 CONTROL (48) FECHA de VACUNACION _____ (52-57) _____ (56-63) _____
 _____ (70-75) _____

Dia	Fecha	Temperatura		Malestar	Anorexia	Gastroenteritis	Irritabilidad	Cafeza	I.V.R.S.	Otitis	Conjuntivitis	Linfadenopatía	Reaccion Local*	RASH*			Artralgia	Artritis	* Especifique tipo en esta seccion
		Oral	Rectal											Rubelliforme	Morbiliforme	Otras Reacciones			
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Al terminar el estudio, devuelva copia blanca y copia amarilla de este forma (Retenga copia color de rosa para sus archivos)
M. R. HILLEMANN, PhD, DSc
MERCK SHARP & DOHME RESEARCH LABORATORIES
WEST POINT, PENNSYLVANIA, 19456, U.S.A.

Firma del medico: _____
 Nombre del medico (en letra de molde): _____ Fecha: _____

Table 1

Serological Findings Among Children Who Received Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #511)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:										Initially Seropositive to: Measles, Mumps and Rubella		
			Measles-Mumps-Rubella			Measles-Mumps		Measles-Rubella		Mumps-Rubella		Measles Only		Mumps Only	Rubella Only
			Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total	Conversions/ Total			
(Months)															
8	1	1						1/1	1/1						
9	1	1								1/1	1/1				
10	2	2						1/1	1/1					1/1	
11	3	1	1/1	1/1	1/1										
12	2	2	0/1	1/1	1/1			0/1	1/1						
13	3	3	1/1	1/1	1/1			1/1	1/1			0/1			
14	2	2	2/2	2/2	2/2										
17	2	1						0/1	1/1						
18	2	2								1/1	1/1			1/1	
21	1	1												1/1	
(Years)															
2	10	8	2/2	2/2	2/2			1/2	2/2					3/3	1
3	6	6	1/1	1/1	1/1	1/1	1/1			1/1	1/1			3/3	
4	2	2											1/1	1/1	
5	4	4	1/2	1/2	2/2					1/1	1/1		1/1		
6	1	1												1/1	
7	2	2	1/1	1/1	1/1			1/1	1/1						
8	2	2												1/1	1
9	2	2												2/2	
11	2	1						1/1	1/1						
Total	50	44	9/11	10/11	11/11	1/1	1/1	6/9	9/9	4/4	4/4	0/1	2/2	14/14	2
Mean Age:	3.3 Years		(81.8%)	(90.9%)	(100%)	(100%)	(100%)	(66.7%)	(100%)	(100%)	(100%)		(100%)	(100%)	

Overall Conversion Rates

Measles	Mumps	Rubella
16/22	17/18	38/38
(72.7%)	(94.4%)	(100%)

Table 2

Serological Findings Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #511)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:												Initially Seropositive to: Measles, Mumps and Rubella	
			Measles-Mumps-Rubella			Measles-Mumps		Measles-Rubella		Mumps-Rubella		Measles Only	Mumps Only	Rubella Only		
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/Total		Conversions/Total	Conversions/Total	Conversions/Total		
			Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Mumps	Rubella	Total	Total	Total		
(Months)																
11	1	1								1/1	1/1					
12	2	1	1/1	1/1	1/1											
13	1	1						1/1	1/1							
14	2	2								1/1	1/1				1/1	
16	1	1						0/1	1/1							
17	1	1								0/1	1/1					
18	3	3	1/1	1/1	1/1			1/1	1/1	1/1	1/1					
21	1	1								1/1	1/1					
(Years)																
2	9	9	1/2	1/2	2/2			1/1	1/1	1/1	1/1				5/5	
3	7	7								4/4	4/4	1/1			2/2	
4	7	6	1/1	1/1	1/1	1/1	1/1			2/2	2/2				2/2	
5	8	8						1/1	1/1	1/1	1/1				6/6	
6	6	5												1/1	3/3	1
7	1	1													1/1	
Total	50	47	4/5	4/5	5/5	1/1	1/1	4/5	5/5	12/13	13/13	1/1	1/1	20/20	1	
Mean Age:	3.3 Years		(80.0%)	(80.0%)	(100%)	(100%)	(100%)	(80.0%)	(100%)	(92.3%)	(100%)	(100%)	(100%)	(100%)		

Overall Conversion Rates

Measles	Mumps	Rubella
10/12	18/20	43/43
(83.3%)	(90.0%)	(100%)

Table 3

Serological Findings Among Children Who Received Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #511)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:									Initially Seropositive to: Measles, Mumps and Rubella	
			Measles-Mumps-Rubella			Measles-Rubella		Mumps-Rubella		Measles Only	Mumps Only		Rubella Only
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/Total	Conversions/Total		Conversions/Total
			Measles	Mumps	Rubella	Measles	Rubella	Mumps	Rubella	Total	Total	Total	
(Months)													
11	1	1										1/1	
13	1	1										1/1	
17	1	1				1/1	1/1						
19	1	1						1/1	1/1				
(Years)													
2	8	8	1/1	1/1	1/1			0/1	1/1	1/1	1/1	1/1	3
3	8	8						2/2	2/2			4/4	2
4	11	11				2/2	2/2	3/3	3/3			4/4	2
5	8	8	1/1	1/1	1/1			2/4	4/4		1/1	1/1	1
6	4	4									1/1	2/2	1
7	5	4						1/1	1/1		1/1	1/1	1
9	1	1										1/1	
11	1	1										1/1	
Total	50	49	2/2	2/2	2/2	3/3	3/3	9/12	12/12	1/1	4/4	17/17	10
Mean Age: 4.2 Years			(100%)	(100%)	(100%)	(100%)	(100%)	(75.0%)	(100%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

Measles	Mumps	Rubella
6/6	15/18	34/34
(100%)	(83.3%)	(100%)

1/27/78

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #511)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	2
5	
10	1
20	3
40	1
80	3
160	1
Total 11	
Geometric Mean Titer: 20.5	

Mumps (Neut)	
Post-Titer Distribution	Number of Children
<2	1
2	3
4	2
8	3
16	1
32	1
Total 11	
Geometric Mean Titer: 4.8	

Rubella (HI)	
Post-Titer Distribution	Number of Children
128	4
256	5
>512	2
Total 11	
Geometric Mean Titer: >225.7	

1/27/78

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #511)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	1
5	
10	
20	
40	3
80	
160	1
Total	5
Geometric Mean Titer: 25.2	

Mumps (Neut)	
Post-Titer Distribution	Number of Children
<2	1
2	
4	1
8	1
16	
32	
64	2
Total	5
Geometric Mean Titer: 10.6	

Rubella (HI)	
Post-Titer Distribution	Number of Children
128	3
256	2
Total	5
Geometric Mean Titer: 168.9	

1/27/78

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #511)

Measles (HI)	
Post-Titer Distribution	Number of Children
20	1
40	1
Total 2	
Geometric Mean Titer: 28.3	

Mumps (Neut)	
Post-Titer Distribution	Number of Children
8	2
Total 2	
Geometric Mean Titer: 8.0	

Rubella (HI)	
Post-Titer Distribution	Number of Children
256	2
Total 2	
Geometric Mean Titer: 256.0	

1/27/78

Table 7

Maximum Temperatures Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #511)

Maximum Temperature (°F, Oral)	Total Vaccinees (50 Children)					No. with Max. Temp.	Initially Seronegatives (13 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	48 (96.0%)	44 (88.0)	45 (90.0)	47 (94.0)	50 (100)	35	12 (92.3)	13 (100)	10 (76.9)	13 (100)	13 (100)	9
99 - 100.9	2 (4.0)	6 (12.0)	5 (10.0)	3 (6.0)		15	1 (7.7)		3 (23.1)			4

1/31/78

Table 8

Maximum Temperatures Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-EB11 (Study #511)

Maximum Temperature (°F, Oral)	Total Vaccinees (50 Children)					No. with Max. Temp.	Initially Seronegatives (6 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	47 (94.0%)	42 (84.0)	47 (94.0)	45 (90.0)	48 (96.0)	31	6 (100)	5 (83.3)	6 (100)	5 (83.3)	6 (100)	4
99 - 100.9	3 (6.0)	8 (16.0)	3 (6.0)	5 (10.0)	2 (4.0)	19		1 (16.7)		1 (16.7)		2

1/31/78

Table 9

Maximum Temperatures Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #511)

Maximum Temperature (°F, Oral)	Total Vaccinees (50 Children)						Initially Seronegatives (2 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	50 (100%)	40 (80.0)	47 (94.0)	50 (100)	47 (94.0)	36	2 (100)	2 (100)	2 (100)	2 (100)	2 (100)	2
99 - 100.9		10 (20.0)	3 (6.0)		3 (6.0)	14						0

1/31/78

Table 10

Clinical Complaints Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (13 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache	1 (2.0%)	1 (2.0)	1 (2.0)	1 (2.0)		4						0
Irritability	5 (10.0)	8 (16.0)	6 (12.0)	5 (10.0)		18	2 (15.4)	3 (23.1)	3 (23.1)	1 (7.7)		7
Malaise	7 (14.0)	9 (18.0)	4 (8.0)	4 (8.0)		17	3 (23.1)	3 (23.1)	3 (23.1)	2 (15.4)		7
Anorexia		1 (2.0)		1 (2.0)		2				1 (7.7)		1
Upper Respiratory Illness	2 (4.0)	6 (12.0)	3 (6.0)	1 (2.0)		9			2 (15.4)			2
Lower Respiratory Illness	1 (2.0)	1 (2.0)				1	1 (7.7)	1 (7.7)				1
Gastrointestinal Illness	1 (2.0)	3 (6.0)	1 (2.0)	4 (8.0)	2 (4.0)	7			1 (7.7)	2 (15.4)	1 (7.7)	3
Persons with Complaint:	7 (14.0)	9 (18.0)	7 (14.0)	8 (16.0)	2 (4.0)	21	3 (23.1)	3 (23.1)	4 (30.8)	2 (15.4)	1 (7.7)	8
Persons with No Complaint:	43 (86.0)	41 (82.0)	43 (86.0)	42 (84.0)	48 (96.0)	29	10 (76.9)	10 (76.9)	9 (69.2)	11 (84.6)	12 (92.3)	5

Table 11

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-2811 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (6 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache	2 (4.0%)	1 (2.0)	4 (8.0)	2 (4.0)		8		1 (16.7)				1
Irritability	2 (4.0)	9 (18.0)	4 (8.0)	5 (10.0)	3 (6.1)	18		1 (16.7)		1 (16.7)		2
Malaise	2 (4.0)	7 (14.0)	2 (4.0)	3 (6.0)		12		1 (16.7)		1 (16.7)		2
Anorexia		1 (2.0)				1						0
Upper Respiratory Illness	2 (4.0)	4 (8.0)				4						0
Lower Respiratory Illness		1 (2.0)	1 (2.0)			1						0
Gastrointestinal Illness	1 (2.0)	3 (6.0)	2 (4.0)	1 (2.0)		5						0
Persons with Complaint:	2 (4.0)	11 (22.0)	7 (14.0)	6 (12.0)	3 (6.1)	20	0	1 (16.7)	1 (16.7)	1 (16.7)	0	3
Persons with No Complaint:	48 (96.0)	39 (78.0)	43 (86.0)	44 (88.0)	46 (93.9)	30	6 (100)	5 (83.3)	5 (83.3)	5 (83.3)	5 (100)	3
Negative Surveillance	0	0	0	0	1	0	0	0	0	0	1	0

Table 12

Clinical Complaints Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (2 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache		2 (4.0%)	4 (8.0)			6			1 (50.0)			1
Irritability	1 (2.0)	9 (18.0)	3 (6.0)	1 (2.0)	2 (4.0)	12						0
Malaise	2 (4.0)	6 (12.0)	4 (8.0)		3 (6.0)	13			1 (50.0)			1
Anorexia	1 (2.0)	3 (6.0)	1 (2.0)			5						0
Upper Respiratory Illness	1 (2.0)	2 (4.0)				2						0
Lower Respiratory Illness		1 (2.0)				1						0
Otitis	1 (2.0)					1						0
Gastrointestinal Illness	1 (2.0)	1 (2.0)	1 (2.0)			2						0
Persons with Complaint:	2 (4.0)	11 (22.0)	6 (12.0)	1 (2.0)	3 (6.0)	17	0	0	1 (50.0)	0	0	1
Persons with No Complaint:	48 (96.0)	39 (78.0)	44 (88.0)	49 (98.0)	47 (94.0)	33	2 (100)	2 (100)	1 (50.0)	2 (100)	2 (100)	1

MEMO

To File Location Date 2/6/78
From T. Schofield Location
Subject Statistical Analysis - Study #511, Combined Live Measles-Mumps-Rubella Virus Vaccine

Significant differences in seroconversion rates for measles, mumps, and rubella and clinical reaction rates among vaccinees receiving three lots of combined live measles-mumps-rubella vaccine were investigated. Lots of vaccine were:

Lot #60664/C-E810

Lot #60665/C-E811

Lot #60666/C-E812

No significant differences exist among the three lots with respect to these rates.

Analyses of variance were performed on post-titer values of children who were initially seronegative to the individual components. The log transformation was used in each analysis. No significant differences exist among the groups (lots) for any of the three components.

A multivariate analysis was performed on post-titer values of triple-negative vaccinees. Again, the log transformation was applied. There was no significant difference among the groups.



T.S.
6801



Reference No. 8

Program: Study #513 - To measure antibody and clinical responses to three consecutive lots of combined measles-mumps-rubella virus vaccine.

Vaccine: Combined live measles-mumps-rubella (RA 27/3) virus vaccine, lyophilized

Lot #60664/C-E810

Lot #60665/C-E811

Lot #60666/C-E812

Responsible Clinical Investigator:

Robert E. Weibel, M.D.
Director, Division of Preventive Medicine
Joseph Stokes, Jr. Research Institute
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, Pennsylvania 19104

Study Locations:

Lankenau Pediatric Clinic, Philadelphia, Pennsylvania
G. A. Starkweather, M.D., Havertown, Pennsylvania
Elizabeth M. Craven, M.D., Wilmington, Delaware
Pediatric Medical Associates, Havertown, Pennsylvania
Children's Hospital of Philadelphia, Philadelphia, Pennsylvania

Date Study Initiated: June 15, 1977

Date Study Completed: In Progress

Study Procedure:

One hundred sixty-three children, 11 months to 7 years of age, have been included in the study thus far. Each received a 0.5 ml subcutaneous dose of combined live measles-mumps-rubella virus vaccine. Blood samples were obtained on day of vaccination and 6 weeks after vaccination. Each child was followed 6 weeks for clinical complaints. The study continues in progress.

Clinical Protocol - Study #513Combined Live Measles-Mumps-Rubella (RA 27/3)Virus Vaccine

Program: Combined live measles-mumps-rubella virus vaccine

Purpose: To measure antibody and clinical responses to three consecutive lots of vaccine.

Vaccine: Combined live measles-mumps-rubella virus vaccine, lyophilized,
Lot. No. 60664/C-E810
Lot. No. 60665/C-E811
Lot. No. 60666/C-E812

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water which is supplied in prefilled syringes.

CAUTION: The vaccine contains egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. The vaccine contains neomycin and should not be given to persons sensitive to neomycin. Persons with leukemia or other immunologic disorder and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccine should not be given to persons with a febrile respiratory illness or other active febrile infection.

Keep dried vaccine stored at -20° C until used.

Keep dried vaccine at 4° C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of up to 150 children with a negative history for vaccination and illness caused by measles, mumps and rubella viruses. The children should range from 1 to 6 years of age.

Approximately 25 to 50 children will receive each of the three vaccine lots.

Informed written consent will be obtained from a parent or guardian of each child who participates in the study.

Clinical Protocol - Study #513
 Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Procedure:
 (Continued)

Each child will receive a 0.5 ml subcutaneous injection of vaccine.

Bleeding samples (10-15 ml) will be obtained from each child immediately before and 6 weeks after vaccination.

Each child will be followed clinically for local and systemic complaints occurring within 6 weeks after vaccination. Observations should include special notation for rash, nodes, arthralgia, arthritis, fever, malaise and anorexia. All complaints should be recorded on the case report form.

Schedule:

Time	Action - All Persons
Day 0	Bleed 10-15 ml Vaccinate 0.5 ml, subcutaneously
Days 0-42	Clinical follow-up for local and systemic complaints
Week 6	Bleed 10-15 ml

Serology:

Levels of circulating measles and rubella antibodies will be determined by hemagglutination-inhibition test. Levels of mumps antibody before and after vaccination will be determined by serum neutralization test.

Clinical Forms: Attached.

Adverse
 Reactions:

Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Arlene A. McLean, telephone (215) 699-5311, Ext. 6383.

Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.



M. R. Hilleman, Ph.D.

SYMPTOM RECORD

RUBELLA STUDY NO. _____

NAME _____ (Last) _____ (First) _____ (Middle) CASE NO. _____

DAY	DATE	Temperature		NONE	RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	VOMITING	DIARRHEA	NAUSEA	RASH	SORE JOINTS	SORE ARM (at shot)*	HEADACHE	ACHINESS	FEVER	LOSS OF APETITE	* Describe	COMMENTS
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral (Check One)																			
INSTRUCTIONS ON REVERSE SIDE																						
0																						
1																						
2																						
3																						
4																						
5																						
6																						
7																						
8																						
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39																						
40																						
41																						
42																						

If fever or unusual reaction develops, call:

PLEASE RETURN FOR FOLLOW-UP VISIT ON: _____

BE SURE TO BRING THIS RECORD ALONG WITH YOU.

REGISTRATION

Study No. _____
(1-3)

Case No. _____
(5-9)

CT 2	Name	Sex (35) M F	Birthdate (36-41) mo day yr	(46-47)
	Address			Telephone

Date of Vaccination _____ (54-59)	Pre _____	SEROLOGY:	
Lot No. _____ (49-51)	Post _____	_____	_____
Dose & Route _____ (45)	_____	_____	_____

INDICATE IF THIS CHILD:

Had disease	<input type="checkbox"/> measles	<input type="checkbox"/> mumps	<input type="checkbox"/> rubella
Been vaccinated	<input type="checkbox"/> measles	<input type="checkbox"/> mumps	<input type="checkbox"/> rubella
Been exposed	<input type="checkbox"/> measles	<input type="checkbox"/> mumps	<input type="checkbox"/> rubella
Date of exposure	_____	_____	_____

INSTRUCTIONS FOR COMPLETING SYMPTOM RECORD (Reverse side):

1. Please fill in the date each day.
2. Please take temperature once daily at the same time and record exact thermometer reading.
3. If no symptoms are present, place a check (✓) under "NONE" beside that day's date.
4. If a symptom is present place a check (✓) under it beside that day's date.
5. Describe other symptoms and any RASH in the space under "COMMENTS."
6. THIS IS VERY IMPORTANT INFORMATION. Please do not misplace this card.

Please return completed forms to: M. R. HILLEMAN, PhD, DSc MERCK SHARP & DOHME RESEARCH LABORATORIES WEST POINT, PENNSYLVANIA, 19486, U.S.A.	Physician's Signature	Date
	Physician's Name (Type or Print)	

Table 1

Serological Findings Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #513)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:						Initially Seropositive to:	
			Measles-Mumps-Rubella			Measles-Rubella		Measles Only	Rubella Only	Measles Mumps and Rubella
			Conversions/Total			Conversions/Total		Conversions/Total	Conversions/Total	
Measles	Mumps	Rubella	Measles	Rubella	Total	Total				
(Months)										
12	2	2	2/2	2/2	2/2					
14	8	8	5/5	5/5	5/5	3/3	3/3			
15	21	20	11/12	11/12	12/12	6/6	6/6	2/2		
16	4	4	2/2	2/2	2/2	2/2	2/2			
17	7	7	6/6	6/6	6/6	1/1	1/1			
18	2	2				2/2	2/2			
19	1	1	1/1	1/1	1/1					
20	2	2	1/2	2/2	2/2					
21	1	0								
(Years)										
3	1	1				1/1	1/1			
4	1	1							1/1	
5	1	1				1/1	1/1			
6	1	1							1/1	
7	1	0								
Total	53	50	28/30	29/30	30/30	16/16	16/16	2/2	2/2	0
Mean Age:	1.7 Years		(93.3%)	(96.7%)	(100%)	(100%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Mumps</u>	<u>Rubella</u>
46/48	29/30	48/48
(95.8%)	(96.7%)	(100%)

1/27/78

Table 2

Serological Findings Among Children Who Received Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #513)

Age (Months)	No. Vacc.	No. Serol. Tested	Initially Seronegative to:							Initially Seropositive to:	
			Measles-Mumps-Rubella			Measles-Mumps		Measles-Rubella		Measles Only	Measles Mumps and Rubella
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/ Total	
Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Total				
12	2	2	2/2	2/2	2/2						
13	1	1								1/1	
14	5	5	4/4	4/4	4/4			1/1	1/1		
15	21	21	15/15	14/15	15/15	2/2	2/2	4/4	4/4		
16	7	7	3/3	3/3	3/3	1/1	1/1	3/3	3/3		
17	4	4	3/3	3/3	3/3			1/1	1/1		
19	2	1	0/1	1/1	0/1						
20	1	0									
21	3	3	1/1	1/1	1/1	1/1	1/1	1/1	1/1		
22	3	3	3/3	3/3	3/3						
(Years)											
2	2	2	1/1	1/1	1/1						1
4	3	1	1/1	1/1	1/1						
Total	54	50	33/34	33/34	33/34	4/4	4/4	10/10	10/10	1/1	1
Mean Age:	1.5 Years		(97.1%)	(97.1%)	(97.1%)	(100%)	(100%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

Measles	Mumps	Rubella
48/49	37/38	43/44
(98.0%)	(97.4%)	(97.7%)

1/27/78

Table 3

Serological Findings Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E#12 (Study #513)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:									Initially Seropositive to: Measles Mumps and Rubella	
			Measles-Mumps-Rubella			Measles-Mumps		Measles-Rubella		Measles Only	Mumps Only		Rubella Only
			Conversions/Total			Conversions/Total		Conversions/Total		Conversions/Total	Conversions/Total		Conversions/Total
			Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Total	Total	Total	
(Months)													
11	1	1	1/1	1/1	1/1								
12	1	1	1/1	1/1	1/1								
13	1	0											
14	6	6	5/5	5/5	5/5	1/1	1/1						
15	26	25	18/19	18/19	18/19	1/1	1/1	4/4	4/4			1/1	
16	9	7	4/4	4/4	4/4			2/2	2/2	1/1			
17	4	3	1/1	1/1	1/1	1/1	1/1			1/1			
19	2	2	1/1	1/1	1/1					1/1			
20	1	1						1/1	1/1				
23	2	2						2/2	2/2				
(Years)													
2	1	1									1/1		
4	2	2	1/1	1/1	1/1			1/1	1/1				
Total	56	51	32/33	32/33	32/33	3/3	3/3	10/10	10/10	3/3	1/1	1/1	0
Mean Age:	1.4 Years		(97.0%)	(97.0%)	(97.0%)	(100%)	(100%)	(100%)	(100%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Mumps</u>	<u>Rubella</u>
48/49	36/37	43/44
(98.0%)	(97.3%)	(97.7%)

1/27/78

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #513)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	2
5	
10	
20	1
40	7
80	8
160	8
>320	4
Total	30
Geometric Mean Titer: >70.2	

Mumps (Neut)	
Post-Titer Distribution	Number of Children
<2	1
2	
4	2
8	6
16	7
32	6
64	4
>64	4
Total	30
Geometric Mean Titer: >19.2	

Rubella (HI)	
Post-Titer Distribution	Number of Children
16	1
32	1
64	
128	6
256	9
>512	13
Total	30
Geometric Mean Titer: >256.0	

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Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #513)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	1
5	
10	
20	6
40	2
80	16
160	4
>320	5
Total	34
Geometric Mean Titer: <u>>70.3</u>	

Mumps (Neut)	
Post-Titer Distribution	Number of Children
<2	1
2	2
4	1
8	3
16	7
32	8
64	5
>64	7
Total	34
Geometric Mean Titer: <u>>22.6</u>	

Rubella (HI)	
Post-Titer Distribution	Number of Children
<8	1
8	
16	
32	1
64	3
128	6
256	12
>512	11
Total	34
Geometric Mean Titer: <u>>200.4</u>	

1/27/78

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps, and Rubella, Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #513)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	1
5	
10	2
20	5
40	5
80	8
160	6
>320	6
Total	33
Geometric Mean Titer:	>65.8

Mumps (Neut)	
Post-Titer Distribution	Number of Children
<2	1
2	1
4	1
8	2
16	7
32	8
64	3
>64	10
Total	33
Geometric Mean Titer:	>25.9

Rubella (HI)	
Post-Titer Distribution	Number of Children
<8	1
8	
16	
32	
64	3
128	1
256	14
>512	14
Total	33
Geometric Mean Titer:	>250.7

1/27/78

Table 7

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #513)

Maximum Temperature (°F, Oral)	Total Vaccinees (33 Children)					No. with Max. Temp.	Initially Seronegatives (30 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	30 (60.0%)	22 (44.0)	36 (72.0)	27 (54.0)	31 (62.0)	17	18 (60.0)	11 (36.7)	20 (66.7)	14 (46.7)	18 (60.0)	9
99 - 100.9	17 (34.0)	22 (44.0)	13 (26.0)	19 (38.0)	17 (34.0)	21	10 (33.3)	15 (50.0)	9 (30.0)	13 (43.3)	11 (36.7)	12
101 - 102.9	2 (4.0)	5 (10.0)		3 (6.0)	2 (4.0)	10	1 (3.3)	3 (10.0)		3 (10.0)	1 (3.3)	8
103 - 104.0	1 (2.0)			1 (2.0)		2	1 (3.3)					1
Fever - Temp. Not Taken		1 (2.0)	1 (2.0)			0		1 (3.3)	1 (3.3)			0
Not Taken	3	3	3	3	3	3	0	0	0	0	0	0

Case #	Max. Temp.	Days	Clinical Complaint	Serology		
				Measles	Mumps	Rubella
(b) (6)	102.0	42	Anorexia, Teething	<5	80	2 32 <8 >512
	102.2	33-35	Gastrointestinal Illness, Irritability, Anorexia, Fatigue	<5	>320	<2 32 <8 256
	102.6	7-10	Gastrointestinal Illness, Anorexia, Teething	<5	160	<2 16 <8 256
	102.4	6-8	Sores on Face	<5	160	<2 32 <8 256
	102.0	5	No Clinical Complaints	<5	80	2 64 <8 256
	102.0	8-9	Gastrointestinal Illness	<5	40	<2 8 <8 256
	103.0	20-25	Upper Respiratory Illness	<5	40	2 >64 <8 256
	102.0	18-20	Upper Respiratory Illness	<5	80	<2 16 <8 256
	104.0	0-4	Upper Respiratory Illness, Irritability, Anorexia	<5	80	<2 64 <8 128

Table 8

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-2811 (Study #513)

Maximum Temperature (°F, Oral)	Total Vaccinees (54 Children)						Initially Seronegatives (34 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	34 (66.7%)	28 (54.9)	37 (72.5)	35 (68.6)	37 (72.5)	18	22 (64.7)	18 (52.9)	22 (64.7)	22 (64.7)	22 (64.7)	11
99 - 100.9	14 (27.5)	15 (29.4)	14 (27.5)	14 (27.5)	12 (23.5)	21	9 (26.5)	11 (32.4)	12 (35.3)	12 (35.3)	10 (29.4)	16
101 - 102.9	2 (3.9)	7 (13.7)		2 (3.9)	1 (2.0)	10	2 (5.9)	4 (11.8)			1 (2.9)	5
103 - 104.0		1 (2.0)			1 (2.0)	2		1 (2.9)			1 (2.9)	2
Fever - Temp. Not Taken	1 (2.0)					0	1 (2.9)					0
Not Taken	3	3	3	3	3	3	0	0	0	0	0	0

Case #	Max. Temp.	Days	Clinical Complaint	Serology					
				Measles	Mumps	Rubella	Measles	Mumps	Rubella
(b) (6)	102.0	8-9	Irritable	NS	NS	NS	NS	NS	NS
	102.0	7-9	Gastrointestinal Illness	<5	80	<2	16	<8	32
	102.6	2-8	Gastrointestinal Illness, Nonspecific Rash	<5	80	<2	64	<8	256
	104.0	3-8	Upper Respiratory Illness, Ophthalmopathy, Gastrointestinal Illness, Anorexia	<5	20	<2	32	<8	256
	103.0	28-34	Teething	<5	80	<2	>64	<8	>512
	102.2	4-11	Upper Respiratory Illness	<5	40	<2	2	<8	256

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Table 9

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #513)

Maximum Temperature (°F, Oral)	Total Vaccinees (56 Children)					No. with Max. Temp.	Initially Seronegatives (33 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	31 (57.4X)	22 (40.7)	37 (68.5)	32 (59.3)	26 (48.1)	15	15 (45.5)	9 (27.3)	19 (57.6)	14 (42.4)	11 (33.3)	5
99 - 100.9	20 (37.0)	22 (40.7)	16 (29.6)	22 (40.7)	21 (38.9)	24	16 (48.5)	16 (48.5)	14 (42.4)	19 (57.6)	19 (57.6)	19
101 - 102.9	3 (5.6)	7 (13.0)			6 (11.1)	14	2 (6.1)	6 (18.2)			2 (6.1)	8
103 - 104.0		1 (1.9)			1 (1.9)	1		1 (3.0)			1 (3.0)	1
Fever - Temp. Not Taken		2 (3.7)	1 (1.9)			0		1 (3.0)				0
Not Taken	2	2	2	2	2	2	0	0	0	0	0	0

Case #	Max. Temp.	Days	Clinical Complaint	Serology					
				Measles	Mumps	Rubella	Measles	Mumps	Rubella
(b) (6)	102.0	12-13	Herpes-Type Rash	<5	40	<2	32	<8	256
	104.0	8-9	Measles-Like Rash, Anorexia	<5	80	<2	>64	<8	64
	103.0	42	Upper Respiratory Illness, Non-Specific Rash, Anorexia						
	102.0	30-35	Gastrointestinal Illness	NS	NS	NS	NS	NS	NS
	102.0	0-7	No Clinical Complaints	<5	80	<2	16	<8	128
	102.2	1-4	Upper Respiratory Illness, Ophthalmopathy, Anorexia	<5	40	<2	16	<8	256
	102.2	10	Upper Respiratory Illness, Otitis	<5	80	<2	64	<8	256
	102.0	1-3	Upper Respiratory Illness, Headache, Anorexia, Soreness at Injection Site	NT	NT	NT	NT	NT	NT

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Table 10

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #513)

Clinical Complaint	Total Vaccinees (53 Children)					No. with Complaint	Initially Seronegatives (30 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (3.9%)					2	1 (3.3)					1
Soreness	2					2	1					1
Systemic:												
Arthralgia	1 (2.0)	1 (2.0)				1						0
Measles-Like Rash		6 (11.8)	1 (2.0)	1 (2.0)		6	4 (13.3)	1 (3.3)	1 (3.3)			4
Headache		1 (2.0)				1						0
Irritability	4 (7.8)	2 (3.9)	1 (2.0)	2 (3.9)	2 (3.9)	8	4 (13.3)	2 (6.7)	1 (3.3)	2 (6.7)	1 (3.3)	7
Anorexia	4 (7.8)	3 (5.9)	1 (2.0)	2 (3.9)	5 (9.8)	10	2 (6.7)	2 (6.7)		2 (6.7)	3 (10.0)	7
Disturbed Sleep			1 (2.0)		1 (2.0)	1						0
Fatigue		1 (2.0)			1 (2.0)	1		1 (3.3)			1 (3.3)	1
Myalgia	1 (2.0)	1 (2.0)				1						0
Upper Respiratory Illness	9 (17.6)	12 (23.5)	7 (13.7)	12 (23.5)	11 (21.6)	25	4 (13.3)	7 (23.3)	6 (20.0)	7 (23.3)	8 (26.7)	14
Otitis				1 (2.0)		1				1 (3.3)		1
Ophthalmopathy	1 (2.0)	1 (2.0)		1 (2.0)	1 (2.0)	2		1 (3.3)		1 (3.3)	1 (3.3)	1
Gastrointestinal Illness	12 (23.5)	11 (21.6)	2 (3.9)	4 (7.8)	5 (9.8)	18	9 (30.0)	9 (30.0)	1 (3.3)	3 (10.0)	4 (13.3)	15
Nonspecific Rash	5 (9.8)	4 (7.8)	4 (7.8)	6 (11.8)	8 (15.7)	15	2 (6.7)	4 (13.3)	4 (13.3)	5 (16.7)	5 (16.7)	10
Sores on Face		1 (2.0)				1		1 (3.3)				1
Allergy	1 (2.0)		1 (2.0)			2	1 (3.3)		1 (3.3)			2
Teething	2 (3.9)	4 (7.8)	1 (2.0)	2 (3.9)	3 (5.9)	9	1 (3.3)	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	7
Herpes-Type Rash		1 (2.0)		1 (2.0)		2		1 (3.3)		1 (3.3)		2
Persons with Complaint:	24 (47.1)	27 (52.9)	12 (23.5)	18 (35.3)	19 (37.3)	39	14 (46.7)	19 (63.3)	9 (30.0)	12 (40.0)	13 (43.3)	25
Persons with No Complaint:	27 (52.9)	24 (47.1)	39 (76.5)	33 (64.7)	32 (62.7)	12	16 (53.3)	11 (36.7)	21 (70.0)	18 (60.0)	17 (56.7)	5
Negative Surveillance	2	2	2	2	2	2	0	0	0	0	0	0

Table 11

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #513)

Clinical Complaint	Total Vaccinees (54 Children)					No. with Complaint	Initially Seronegatives (34 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (3.8)					2	2 (5.9)					2
Soreness	1					1	1					1
Erythema and Soreness	1					1	1					1
Systemic:												
Lymphadenopathy	2 (3.8)	1 (1.9)				3	1 (2.9)	1 (2.9)				2
Measles-Like Rash		5 (9.6)	4 (7.7)	1 (1.9)		7		3 (8.8)	2 (5.9)			4
Irritability	4 (7.7)	6 (11.5)	1 (1.9)	1 (1.9)	2 (3.8)	9	4 (11.8)	4 (11.8)		1 (2.9)	2 (5.9)	7
Malaise	1 (1.9)	1 (1.9)				1	1 (2.9)	1 (2.9)				1
Anorexia	5 (9.6)	5 (9.6)	3 (5.8)	2 (3.8)	4 (7.7)	13	3 (8.8)	4 (11.8)	2 (5.9)	1 (2.9)	3 (8.8)	9
Disturbed Sleep	1 (1.9)	1 (1.9)	1 (1.9)			2	1 (2.9)	1 (2.9)				1
Fatigue	2 (3.8)					2	2 (5.9)					2
Upper Respiratory Illness	10 (19.2)	9 (17.3)	5 (9.6)	10 (19.2)	11 (21.2)	25	4 (11.8)	6 (17.6)	4 (11.8)	6 (17.6)	7 (20.6)	15
Otitis	2 (3.8)	2 (3.8)	2 (3.8)	1 (1.9)	1 (1.9)	4	2 (5.9)	1 (2.9)	1 (2.9)	1 (2.9)	1 (2.9)	2
Ophthalmopathy	1 (1.9)	3 (5.8)		1 (1.9)	1 (1.9)	5	1 (2.9)	2 (5.9)		1 (2.9)	1 (2.9)	4
Gastrointestinal Illness	9 (17.3)	10 (19.2)	5 (9.6)	4 (7.7)	6 (11.5)	18	6 (17.6)	7 (20.6)	3 (8.8)	3 (8.8)	5 (14.7)	11
Nonspecific Rash	4 (7.7)	3 (5.8)		2 (3.8)	2 (3.8)	7	3 (8.8)	3 (8.8)		2 (5.9)	2 (5.9)	6
Allergy	1 (1.9)					1	1 (2.9)					1
Teething	1 (1.9)	1 (1.9)	1 (1.9)	3 (5.8)	3 (5.8)	4	1 (2.9)	1 (2.9)		1 (2.9)	1 (2.9)	2
Persons with Complaint:	24 (46.2)	26 (50.0)	18 (34.6)	21 (40.4)	18 (34.6)	36	16 (47.1)	18 (52.9)	11 (32.4)	13 (38.2)	12 (35.3)	23
Persons with No Complaint:	28 (53.8)	26 (50.0)	34 (65.4)	31 (59.6)	34 (65.4)	16	18 (52.9)	16 (47.1)	23 (67.6)	21 (61.8)	22 (64.7)	11
Negative Surveillance:	2	2	2	2	2	2	0	0	0	0	0	0

Table 12

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-R812 (Study #513)

Clinical Complaint	Total Vaccinees (56 Children)					No. with Complaint	Initially Seronegatives (33 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	4 (7.4%)					4	3 (9.1)					3
Soreness	4					4	3					3
Systemic:												
Lymphadenopathy				1 (1.9)		1			1 (3.0)			1
Measles-Like Rash		6 (11.1)	2 (3.7)	1 (1.9)		8		4 (12.1)	2 (6.1)	1 (3.0)		6
Headache	1 (1.9)					1						0
Irritability	4 (7.4)	4 (7.4)	3 (5.6)	3 (5.6)	2 (3.7)	8	2 (6.1)	3 (9.1)	2 (6.1)	3 (9.1)	2 (6.1)	5
Anorexia	6 (11.1)	9 (16.7)	1 (1.9)	2 (3.7)	11 (20.4)	20	4 (12.1)	5 (15.2)			9 (27.3)	13
Disturbed Sleep	1 (1.9)	2 (3.7)				2	1 (3.0)	2 (6.1)				2
Fatigue		1 (1.9)		1 (1.9)		1		1 (3.0)		1 (3.0)		1
Myalgia				1 (1.9)	2 (3.7)	2				1 (3.0)	1 (3.0)	1
Upper Respiratory Illness	13 (24.1)	19 (35.2)	13 (24.1)	14 (25.9)	15 (27.8)	30	10 (30.3)	12 (36.4)	9 (27.3)	11 (33.3)	12 (36.4)	20
Otitis	1 (1.9)	2 (3.7)		2 (3.7)	2 (3.7)	5		1 (3.0)		2 (6.1)	2 (6.1)	3
Ophthalmopathy	2 (3.7)	1 (1.9)		1 (1.9)	1 (1.9)	4	1 (3.0)			1 (3.0)	1 (3.0)	2
Gastrointestinal Illness	6 (11.1)	4 (7.4)	4 (7.4)	5 (9.3)	7 (13.0)	18	4 (12.1)		3 (9.1)	4 (12.1)	3 (9.1)	12
Nonspecific Rash	4 (7.4)	8 (14.8)	6 (11.1)	7 (13.0)	6 (11.1)	19	3 (9.1)	5 (15.2)	4 (12.1)	4 (12.1)	4 (12.1)	13
Sore from Venipuncture	1 (1.9)					1	1 (3.0)					1
Teething		3 (5.6)	2 (3.7)	3 (5.6)	3 (5.6)	5		3 (9.1)	2 (6.1)	3 (9.1)	2 (6.1)	4
Herpes-Type Rash		1 (1.9)				1		1 (3.0)				1
Persons with Complaint:	27 (50.0)	33 (61.1)	22 (40.7)	24 (44.4)	25 (46.3)	41	20 (60.6)	22 (66.7)	16 (48.5)	19 (57.6)	17 (51.5)	27
Persons with No Complaint:	27 (50.0)	21 (38.9)	32 (59.3)	30 (55.6)	29 (53.7)	13	13 (39.4)	11 (33.3)	17 (51.5)	14 (42.4)	16 (48.5)	6
Negative Surveillance	2	2	2	2	2	2	0	0	0	0	0	0

MEMO

To File Location Date 2/6/78
From T. Schofield Location
Subject Preliminary Statistical Analysis - Study #513, Combined Live Measles-Mumps-Rubella Virus Vaccine

Significant differences in seroconversion rates for measles, mumps, and rubella and clinical reaction rates among vaccinees receiving three lots of combined live measles-mumps-rubella vaccine were investigated. Lots of vaccine were:

Lot #60664/C-E810
Lot #60665/C-E811
Lot #60666/C-E812

A significant difference exists among the three lots in the incidence of non-specific rash. 15 out of 53 exhibited diaper, heat, or contact rash (28.3%) who received Lot #60664/C-E810; 7 out of 54 (12.9%) who received Lot #60665/C-E811; and 19 out of 56 (33.9%) who received Lot #60666/C-E812. No other rates were significant.

Analyses of variance were performed on post-titer values of children who were initially seronegative to the individual components. The log transformation was used in each analysis. No significant differences exist among the groups (lots) for any of the three components.

A multivariate analysis was performed on the post-titer values of triple-negative vaccinees. Again, the log transformation was applied. There was no significant difference among the groups.



T.S.
6801



Summary No. 1
of
Clinical Investigative Studies
of

Combined Live Measles Virus Vaccine (Moraten Line-ATTENUVAX)
RA 27/3 Rubella Virus Vaccine

for Purpose of Support for
a License to Manufacture and Sell.



M. R. Hilleman, Ph.D.

Prepared: August 11, 1978
Merck Institute for Therapeutic Research
West Point, Pennsylvania

Clinical Investigative Studies of Combined Live
Measles-Rubella (RA 27/3) Virus Vaccine

1. Background

In a separate submission, "Summary No. 2 of Clinical Investigative Studies of RA 27/3 Strain Live Rubella Virus Vaccine for Support of a License to Manufacture and Sell," dated January 11, 1978, and in Addendum No. 1 to that submission dated June 26, 1978, the RA 27/3 strain rubella virus vaccine was shown to be safe and highly effective in eliciting an antibody response in persons of various ages.

In extension of clinical tests with RA 27/3 rubella virus vaccine, studies were conducted to evaluate its immunizing capability when combined with live attenuated Moraten measles virus vaccine (ATTENUVAX). The present submission relates to clinical investigative studies of combined live measles-rubella (RA 27/3) virus vaccine.

All clinical studies were conducted under BB-IND-1015, Combined Live Measles-Rubella (RA 27/3) Virus Vaccine.

2. Lot Numbers of Vaccine Tested

Experimental lot prepared by Virus and Cell Biology Research,
Merck Sharp and Dohme Research Laboratories:

622/C-D764

Consistency lots prepared by Merck Sharp and Dohme Biologicals Manufacturing:

62343/C-F021

62344/C-F022

62345/C-F023

3. Serologic Testing

Serologic determinations were made in the laboratories of Virus and Cell Biology Research, Merck Institute, and in the Control Laboratories of the Merck Sharp and Dohme Division of Merck and Co.

The hemagglutination-inhibition (HI) test was used to determine rubella antibody response. The starting dilution was 1:8.

In most cases, measles antibody determinations were by HI assay with a starting dilution of 1:5. Where noted, sera were retested by serum neutralization test at a starting dilution of 1:2.

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4. Clinical Studies

The clinical studies were conducted under the overall responsibility of Dr. Maurice R. Hilleman, Vice President, Virus and Cell Biology Research, Merck Institute for Therapeutic Research, West Point, Pennsylvania.

The clinical tests were carried out by three groups of workers:

- a. Dr. Robert E. Weibel, Director, Division of Preventive Medicine, Joseph Stokes, Jr. Research Institute, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
- b. Dr. Victor M. Villarejos, Director, Louisiana State University - International Center for Medical Research and Training, San Jose, Costa Rica
- c. Dr. Louis Z. Cooper, Director, Pediatric Service, The Roosevelt Hospital, New York, New York

Clinical studies fall into two main categories:

	<u>Reference</u>
a. Comparison of measles-rubella (RA 27/3) and measles-rubella (HPV-77) vaccines	2
b. Serologic and clinical responses to measles-rubella (RA 27/3) vaccine	1, 3, 4

The clinical studies were carried out by the physicians at the locations in the individual study summaries to follow. The populations employed were defined with respect to age, location and other pertinent parameters.

Subjects were bled initially and again 6 to 8 weeks later. The sera were tested to define the initial serostatus and the subsequent antibody response.

Clinical surveillance was by two procedures. In studies by Drs. Weibel and Cooper, the observations were recorded daily by the mother. The parent was asked to contact the physician should any significant or bothersome reaction occur. In the studies by Dr. Villarejos, observations were made on a routine basis by medical or paramedical personnel; physicians were notified of any significant illness which occurred subsequent to vaccination.

The data presented in the following sections are self-explanatory. The detailed background records are on file in Virus and Cell Biology Research, Merck Institute for Therapeutic Research, West Point, Pennsylvania. These records are available for review at any time.

5. Clinical Study SummariesReference 1 - Study 442 - Dr. Victor Villarejos

Details of the study plan are given in the clinical test protocol. The study was designed to measure antibody and clinical responses to the RA 27/3 rubella component when given alone or combined with mumps and/or measles vaccine. Findings presented in the summary tables indicate excellent antibody response to both virus components among children receiving combined live measles-rubella (RA 27/3) virus vaccine. No significant clinical reactions were noted following vaccination.

Reference 2 - Study 470 - Dr. Louis Cooper

This study is being conducted among children to compare responses to HPV-77 and RA 27/3 rubella vaccines when given alone or combined with live measles virus vaccine. Details of the study plan are given in the clinical test protocol, and results, to date, are presented in the summary tables. The study continues in progress.

Reference 3 - Study 512 - Dr. Victor Villarejos

Study 512 was conducted to measure antibody and clinical responses to three consecutive lots of combined measles-rubella vaccine containing the RA 27/3 rubella component. Study details are given in the clinical protocol. Findings presented in the summary tables indicate excellent antibody response to both components of all three lots of vaccine. No significant clinical reactions were noted.

Reference 4 - Study 514 - Dr. Robert Weibel

Study 514 is being conducted to measure antibody and clinical responses to three consecutive lots of combined measles-rubella vaccine containing the RA 27/3 rubella component. Details of the study plan are given in the clinical test protocol and results are presented in the summary tables. All three lots showed excellent antibody response while no significant clinical reactions were noted.

6. Overall Summary

The total numbers of vaccinations for which supporting data have been given are as follows:

<u>Lot #</u>	<u>No. Vacc.</u>	<u>No. Seroconverting/No. Double Negatives (%)</u>	
		<u>Measles</u>	<u>RA 27/3 Rubella</u>
622	216	59/64 (92)	63/64 (93)
62343	107	46/50 (92)	50/50 (100)
62344	105	45/45 (100)	45/45 (100)
62345	100	49/50 (98)	50/50 (100)
Unknown	30	26/28 (93)	28/28 (100)
Totals	558	225/237 (95)	236/237 (99)

The data show that combined live measles-rubella vaccine containing the RA 27/3 rubella virus component is safe and effective.

Summary of Clinical Tests of Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Study No.	Investigator	Lot No.	Age		No. Vacc.	Antibody Responses among Double Negatives						Reference No.
			Range	Mean (Yrs.)		Measles		Rubella		GMT	GMT	
						No. Conv./ No. Seroneg. (%)	GMT	No. Conv./ No. Seroneg. (%)	GMT			
442	Villarejos	622	1 - 6y	3.7	193	49/54 (91)	49	53/54 (98)	151		1	
470	Cooper	622	14m- 6y	2.0	23	10/10 (100)	57	10/10 (100)	274		2	
512	Villarejos	62343	10m- 9y	4.4	60	12/15 (80)	17	15/15 (100)	308		3	
		62344	11m- 8y	4.3	60	18/18 (100)	40	18/18 (100)	376			
		62345	13m- 6y	4.1	55	16/17 (94)	70	17/17 (100)	289			
514	Weibel	62343	13m- 3y	1.4	47	34/35 (97)	80*	35/35 (100)	312		4	
		62344	14m- 4y	1.8	45	27/27 (100)	78	27/27 (100)	367			
		62345	13m- 4y	1.4	45	33/33 (100)	114	33/33 (100)	415			
		Unknown	13m-10y	1.7	30	26/28 (93)	51*	28/28 (100)	371			
		Totals			558	225/237 (95)	60	236/237 (99)	287			

* GMT based on Measles HI results only.

Reference No. 1

Program: Study #442

Vaccine: Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine
Lot No. 621/C-D763Combined Live Measles-Rubella (RA 27/3) Virus Vaccine
Lot No. 622/C-D764Live Attenuated Rubella (RA 27/3) Virus Vaccine
Lot No. 579/C-D418

Responsible Clinical Investigator:

Victor M. Villarejos, M.D.
Director
Louisiana State University
International Center for Medical
Research and Training
Apartado 10.155
San Jose, Costa Rica

Study Location: Rivas, Nicaragua

Date Study Initiated: January 19, 1976

Date Study Completed: April 28, 1976

Study Procedure:

A total of 589 children, 10 months to 7 years of age, from the open population were included in the study. Each participant received a 0.5 ml subcutaneous dose of one of the three vaccines. Blood samples were obtained prior to and six weeks after vaccination.

Clinical Protocol - Study #442

Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine
Live Attenuated Rubella (RA 27/3) Virus Vaccine

Purpose: To determine antibody and clinical responses to combined live-measles-mumps-rubella (RA 27/3) virus vaccine, to combined live measles-rubella (RA 27/3) virus vaccine, and to live attenuated rubella (RA 27/3) virus vaccine.

Vaccines: a) Combined live measles-mumps-rubella (RA 27/3) virus vaccine
Lot No. 621

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

b) Combined live measles-rubella (RA 27/3) virus vaccine
Lot No. 622

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

c) Live attenuated rubella (RA 27/3) virus vaccine
Lot No. 579

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial of vaccine should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: The combined vaccines contain egg protein and should not be given to persons with known sensitivity to egg, chicken, or chicken feathers. All three vaccines contain neomycin and should not be given to persons with sensitivity to neomycin. Persons with leukemia or other immunologic disorders and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C until used.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccines on ice. Discard unused vaccine 4 hours after rehydration.

Clinical Protocol -
Study #442

-2-

Procedure: The study population will consist of children 1 to 6 years of age.

Children receiving a given vaccine will have a negative history for vaccination with and illness caused by viruses represented in that vaccine. Children will be assigned to receive one of the three vaccines as follows:

<u>Vaccine</u>	<u>Vaccine Lot</u>	<u>No. Children</u>
measles-mumps-rubella	621	150-200
measles-rubella	622	150-200
rubella	579	150-200

Informed consent will be obtained from each child's parent or guardian prior to his participation in the study.

Each child will be bled (10-15 ml) immediately prior to vaccination and 6 weeks following vaccination.

Vaccine dose is 0.5 ml given subcutaneously.

Each child will be followed clinically for 42 days following vaccination. All local and systemic complaints will be recorded on the case report form.

<u>Schedule:</u>	<u>Time</u>	<u>Action</u>
	Day 0	Bleed 10-15 ml, Vaccinate 0.5 ml, subcutaneously.
	Days 0-42	Clinical follow-up for local and systemic reactions.
	Week 6	Bleed 10-15 ml.

Laboratory: Remove sera from clot aseptically and store frozen at -20°C until shipped. It is imperative that sera are sterile to avoid interference with the serologic assay.

Serology: Circulating levels of antibody to each vaccine component will be determined for samples drawn before and after vaccination. Measles and rubella antibody levels will be determined by hemagglutination-inhibition test. Mumps antibody levels will be determined by serum neutralization test.

Clinical Forms: Attached.

Clinical Protocol -
Study #442

-3-

- Adverse Reactions: Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.
- Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pa. 19486.
- Shipping of Sera & Records:
- a) Send sera frozen within insulated containers which are supplied.
 - b) Send sera and records to Dr. Maurice R. Hilleman, Virus and Cell Biology Research, Merck Sharp & Dohme Research Laboratories, West Point, Pa. 19486.
 - c) Alert Dr. Hilleman by cable as soon as possible as to flight number, air bill, and date of arrival.



M. R. Hilleman, Ph.D.

Estudio No. _____
(1-3)

NOTA AL INVESTIGADOR:

PRECAUCIÓN: Use mecanografía o letra de molde. No escriba en esta forma si esta encima de otras formas NCR (semejantes a esta).

1. No escriba en áreas oscuras
2. Asegurese de llenar todos los blancos apropiados.

CT 2	Nombre Completo del Niño	Sexo (35)		Fecha de nacimiento (36-41)			(46-47)
		M	F	día	mes	año	

CT 6
Dupe CT 2
(141)- (5459)

Dirección completa de Padres o Guardián:

CT 2	INDIQUE SI INDIVIDUO HA:	S = Sarampión	P = Paperas	R = Rubéola	Fecha de expuesto	____/____/____
		S (70)	P (71)	R (72)	Fecha de expuesto	____/____/____
	1. Tenido Enfermedad	1	1	1	Fecha de expuesto	____/____/____
	2. Sido Vacunado	2	2	2		
	3. Estado Expuesto (Durante Últimas Cuatro Semanas)	3	3	3		

PERÍODO DE VACUNACIÓN O CONTROL

(48) Vacunado Control

No. de Lote _____ (49-51)

Fecha de vacunación _____ (52-57)

Fecha de primer sangrado (antes de vacunado) _____ (52-57)

Fecha de segundo sangrado (después de vacunado) _____ (58-63)

SEROLOGÍA									
SARAMPIÓN				PAPERAS		RUBÉOLA			
HI		Neut		Neut		HI		Neut	
Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post

Indique si el niño contrajo Sarampión clínico: 1 = Sí 2 = No

Indique si el niño contrajo Paperas clínica: 1 = Sí 2 = No

Indique si el niño contrajo Rubéola clínica: 1 = Sí 2 = No

CT 4 Fecha de comienzo: _____

Quién hizo diagnóstico? _____

Otras quejas u observaciones clínicas:

Después de completadas, devuelva formas a: (Retenga copia rosa para sus archivos)

M. R. HILLEMANN, PhD. DSc
MERCK SHARP & DOHME RESEARCH LABS., WEST POINT, PENNSYLVANIA 19486

Firma del Médico: _____

Nombre del Médico (en letra de molde): _____

Fecha: _____

VACUNACIÓN CONTRA SARAMPIÓN PAPERAS RUBÉOLA

HOJA CLINICA

NO. DE CASO _____

B

FECHA DE VACUNACION _____ / _____ / _____
 día mes año

NOMBRE: _____

DIA	FECHA	Temperatura	Malestar	Anorexia	Gastroenteritis	Irritabilidad	Cefalea	I. V. R. S.	Otitis	Conjuntivitis	Linfadenopatía*	Reacción Local* (Diámetro mm)	Exantema*	RASH*			Artralgia*	Artritis*	*Especifique tipo en esta sección
														Rubelliforme	Morbiliforme				
		24	16	25	08	15	14	01	03	06		12	50	51	52	11	32		
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PRECAUCION: Papel carbón no es negro. Use máquina de escribir o pluma esfográfica con tinta negra. No escriba encima de otras. NOTA: No escriba en áreas oscurecidas.

Al terminar el estudio, devuelva copia blanca y copia amarilla de esta forma, adjuntas a la forma "A" a: (Retenga copia color de rosa para sus archivos)

M.R. Hilleman, PhD, DSc
 MERCK SHARP & DOHME RESEARCH LABORATORIES
 WEST POINT, PENNSYLVANIA, 19486, U.S.A.

Firma del medico: _____
 Nombre del medico (en letra de molde): _____
 Fecha: _____

Table 1

Serological Findings Among Children Who Received Combined Live
Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:			Initially Seropositive to: Measles and Rubella	
			Measles-Rubella		Measles Only		Rubella Only
			Conversions/Total		Conversions/ Total		Conversions/ Total
			Measles	Rubella			
1 Year	22	16	11/11	11/11		4/4	1
2 Years	20	16	7/9	9/9	2/2	3/3	2
3 Years	46	36	14/16	15/16	1/1	13/13	6
4 Years	40	31	5/5	5/5	2/2	20/20	4
5 Years	28	19	5/5	5/5	1/1	11/11	2
6 Years	37	24	7/8	8/8	4/4	9/9	3
Total	193	142	49/54	53/54	10/10	60/60	18
Mean Age:	3.7 Years		(90.7%)	(98.1%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
59/64 (92.2%)	113/114 (99.1%)

Table 2

Serological Findings Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:											Initially Seropositive to: Measles Mumps and Rubella		
			Measles-Mumps-Rubella Conversions/Total			Measles-Mumps Conversions/Total		Measles-Rubella Conversions/Total		Mumps-Rubella Conversions/Total		Measles Only Conversions/ Total	Mumps Only Conversions/ Total		Rubella Only Conversions/ Total	
			Measles	Mumps	Rubella	Measles	Mumps	Measles	Rubella	Mumps	Rubella	Total	Total		Total	
10 Months	1	0														
11 Months	2	2	1/1	1/1	1/1			1/1	1/1							
1 Year	29	21	7/7	7/7	7/7			4/5	5/5	3/3	3/3		2/2	3/3		1
2 Years	18	15	3/3	3/3	3/3	1/1	1/1	4/4	4/4	2/3	3/3			3/3		1
3 Years	41	33	6/6	6/6	6/6	1/1	1/1	3/3	3/3	6/6	6/6			14/14		3
4 Years	39	34	2/2	2/2	2/2			5/5	5/5	7/8	8/8	1/1		15/15		3
5 Years	32	25	3/3	2/3	3/3			2/2	2/2	2/3	3/3	2/2		13/13		2
6 Years	36	28	1/1	1/1	1/1			8/8	8/8	2/2	2/2		1/1	15/15		1
7 Years	1	1						1/1	1/1							
Total	199	159	23/23 (100%)	22/23 (95.7%)	23/23 (100%)	2/2	2/2	28/29 (96.6%)	29/29 (100%)	22/25 (88.0%)	25/25 (100%)	3/3	3/3	63/63 (100%)		11
Mean Age:	3.7 Years															

Overall Conversion Rates

Measles	Mumps	Rubella
56/57 (98.2%)	49/53 (92.5%)	140/140 (100%)

12/3/77

Table 3

Distribution of Fold Rises of Hemagglutination-Inhibition Antibody Titers Among Children Who Received Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seropositive			Initially Seronegative			
			Fold Rise		Total	No. Conv.	Failures	Total	Conv. Rate
			>4X	Indet.					
1 Year	13	10		1	1	9		9	9/9
2 Years	17	15		1	1	14		14	14/14
3 Years	30	24		2	2	22		22	22/22
4 Years	38	32	1	1	2	30		30	30/30
5 Years	42	29		3	3	26		26	26/26
6 Years	56	48		8	8	40		40	40/40
7 Years	1	0							
Total	197	158	1	16	17	141	0	141	100%
Mean Age: 4.3 Years									

4/28/77

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children
Who Were Initially Seronegative to Measles and Rubella and Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Measles (HI)		Rubella (HI)	
Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children
<5	5	<8	1
5		8	
10	1	16	
20	9	32	1
40	4	64	3
80	22	128	30
160	9	256	13
320	3	512	6
>640	1		
Total	54		54
Geometric Mean Titer	>48.7		151.2

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles, Mumps and Rubella and Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Measles (HI)		Mumps (Neut.)		Rubella (HI)	
Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children	Post-Vaccination Titer	No. of Children
<5		<2	1	<8	
5		2	4	8	
10		4	4	16	
20	2	8	5	32	1
40	5	16	7	64	4
80	5	32	2	128	9
160	6			256	7
320	5			512	2
Total	23		23		23
Geometric Mean Titer	98.8		7.1		148.8

10/3/77

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Rubella and Who Received Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Rubella (HI)	
Post Vaccination Titer	No. of Children
<8	
8	
16	
32	2
64	20
128	70
256	41
>512	8
Total	141
Geometric Mean Titer	>150.5

Table 7

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (193 Children)						Initially Seronegative to: Measles and Rubella (54 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	146 (76.0)	135 (70.3)	138 (72.3)	123 (64.4)	114 (59.7)	67	42 (77.8)	35 (64.8)	39 (72.2)	38 (70.4)	35 (64.8)	23
99 - 100.9	46 (24.0)	56 (29.2)	53 (27.7)	68 (35.6)	77 (40.3)	124	12 (22.2)	19 (35.2)	15 (27.8)	16 (29.6)	19 (35.2)	31
102.0		1 (0.5)				1						
Not Taken	1	1	2	2	2	1						

Serology

Patient #	Temperature	Day	Clinical Complaint	Measles	Rubella
(b) (6)	102.0	5	Upper Respiratory Illness, Irritability, Malaise	>20 160	>32 256

4/28/77

Table 8

Maximum Temperatures Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (199 Children)						Initially Seronegative to: Measles, Mumps and Rubella (23 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	147 (73.92)	138 (69.3)	160 (81.6)	130 (68.4)	137 (72.5)	83	18 (78.3)	20 (87.0)	23 (100.0)	14 (73.7)	16 (84.2)	16
99 - 100.9	51 (25.6)	57 (28.6)	35 (17.9)	59 (31.1)	52 (27.5)	109	5 (21.7)	3 (13.0)		5 (26.3)	3 (15.8)	7
101 - 102.2		2 (1.0)	1 (0.5)			3						
103 - 104.0	1 (0.5)	2 (1.0)		1 (0.5)		4						
Not Taken			3	9	10					4	4	

Patient #	Temperature	Days	Clinical Complaint	Serology		
				Measles	Mumps	Rubella
(b) (8)	102.2	8	Upper Respiratory Illness, Malaise	>20	320	>8 32 <8 1024
	103.1	20	Irritability, Malaise	>20	160	>8 128 <8 64
	103.1	11	Tonsillitis, Anorexia, Headache, Malaise	>20	>640	<2 4 <8 128
	104.0	1	Irritability, Malaise			Serologies Not Done
	104.0	5	Upper Respiratory Illness, Irritability, Anorexia, Malaise	>20	320	<4 16 <8 256

10/3/77

Table 9

Maximum Temperatures Reported Among Children Who Received Live Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Maximum Temperature (°F, Oral)	Total Vaccinees (197 Children)						Initially Seronegative to: Rubella (141 Children)					
	Days Post-Vaccination					No. with Max. Temp.	Days Post-Vaccination					No. With Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	162 (82.2)	131 (66.5)	148 (75.1)	125 (64.4)	138 (71.5)	67	116 (82.3)	97 (68.8)	110 (78.0)	94 (67.6)	104 (74.8)	51
99-100.9	35 (17.8)	66 (33.5)	48 (24.4)	68 (35.1)	55 (28.5)	128	25 (17.7)	44 (31.2)	30 (21.3)	44 (31.7)	35 (25.2)	88
101 - 102.2			1 (0.5)	1 (0.5)		2			1 (0.7)	1 (0.7)		2
Not Taken				3	4					2	2	

Patient #	Temperature	Day	Clinical Complaint	Serology
(b) (8)	102.2	20	Upper Respiratory Illness, Anorexia, Malaise	<8 128

4/29/77

Table 10

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot No. 622/C-D764 (Study #442)

Clinical Complaint	Total Vaccinees (193 Children)						Initially Seronegative to: Measles and Rubella (54 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Irritability	29 (15.1)	11 (5.7)	6 (3.1)	9 (4.7)	6 (3.1)	52	13 (24.1)	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	18
Malaise	33 (17.2)	21 (10.9)	15 (7.9)	15 (7.9)	7 (3.7)	65	12 (22.2)	8 (14.8)	4 (7.4)	2 (3.7)	1 (1.9)	18
Headache	4 (2.1)	3 (1.6)	2 (1.0)	2 (1.0)		9		1 (1.9)	1 (1.9)			1
Upper Respiratory Illness	1 (0.5)	9 (4.7)	8 (4.2)	8 (4.2)	1 (0.5)	21	1 (1.9)	5 (9.3)	2 (3.7)	1 (1.9)		6
Bronchitis			1 (0.5)	1 (0.5)		1			1 (1.9)	1 (1.9)		1
Otitis	1 (0.5)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	6		2 (3.7)	1 (1.9)			3
Gastrointestinal Illness	5 (2.6)	7 (3.6)	6 (3.1)	4 (2.1)	3 (1.6)	23	1 (1.9)	2 (3.7)	1 (1.9)	1 (1.9)		5
Anorexia	5 (2.6)	4 (2.1)	6 (3.1)	4 (2.1)		17	2 (3.7)	1 (1.9)	1 (1.9)			4
Hepatitis	1 (0.5)	1 (0.5)				1						0
Asthma		1 (0.5)				1						0
Persons with Complaints:	36 (18.8)	24 (12.5)	17 (8.9)	18 (9.4)	8 (4.2)	70	13 (24.1)	9 (16.7)	4 (7.4)	3 (5.6)	1 (1.9)	19
Persons with No Complaints:	156 (81.3)	168 (87.5)	174 (91.1)	173 (90.6)	183 (95.8)	121	41 (75.9)	45 (83.3)	50 (92.6)	51 (94.4)	53 (98.1)	35
Negative Physician Surveillance:	1	1	2	2	2	1						

4/29/77

Table 11

Clinical Complaints Reported Among Children Who Received Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #442)

Clinical Complaint	Total Vaccinees (199 Children)						Initially Seronegative to: Measles, Mumps and Rubella (23 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Irritability	32 (16.1%)	9 (4.5)	2 (1.0)	4 (2.1)		39	5 (21.7)			1 (5.0)		5
Malaise	30 (15.1)	14 (7.0)	3 (1.5)	7 (3.6)	1 (0.5)	43	5 (21.7)	1 (4.3)		2 (10.0)		7
Headache		1 (0.5)	2 (1.0)			2						0
Upper Respiratory Illness	9 (4.5)	11 (5.5)	5 (2.5)	8 (4.1)	5 (2.6)	23	1 (4.3)	1 (4.3)	1 (4.3)	2 (10.0)	1 (5.0)	3
Otitis			2 (1.0)	3 (1.5)		3			1 (4.3)	1 (5.0)		1
Ophthalmopathy		1 (0.5)				1						0
Gastrointestinal Illness	13 (6.5)	7 (3.5)	2 (1.0)	5 (2.6)	1 (0.5)	22		1 (4.3)				1
Anorexia	5 (2.5)	3 (1.5)	2 (1.0)	5 (2.6)		13				1 (5.0)		1
Mild Dermatitis		1 (0.5)				1						0
Persons with Complaints:	49 (24.6)	22 (11.1)	11 (5.5)	19 (9.8)	6 (3.1)	73	6 (26.1)	2 (8.7)	1 (4.3)	4 (20.0)	1 (5.0)	10
Persons with No Complaints:	150 (75.4)	177 (88.9)	188 (94.5)	175 (80.2)	187 (96.9)	123	17 (73.9)	21 (91.3)	22 (95.7)	16 (80.0)	19 (95.0)	12
Negative Physician Surveillance				5	6					3	3	

10/3/77

Table 12

Clinical Complaints Reported Among Children Who Received Live
Attenuated Rubella (RA 27/3) Virus Vaccine, Lot No. 579/C-D418 (Study #442)

Clinical Complaint	Total Vaccinees (197 Children)						Initially Seronegative to: Rubella (141 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Irritability	22 (11.2)	4 (2.0)	3 (1.5)	5 (2.6)	2 (1.0)	32	15 (10.6)	4 (2.8)	2 (1.4)	2 (1.4)	1 (0.7)	23
Malaise	28 (14.2)	10 (5.1)	5 (2.5)	9 (4.6)	4 (2.1)	46	19 (13.5)	9 (6.4)	2 (1.4)	5 (3.5)	2 (1.4)	32
Headache	2 (1.0)	1 (0.5)		3 (1.5)	1 (0.5)	6	1 (0.7)			1 (0.7)		2
Upper Respiratory Illness	4 (2.0)	8 (4.1)	1 (0.5)	6 (3.1)	2 (1.0)	15	3 (2.1)	6 (4.3)	1 (0.7)	5 (3.5)	2 (1.4)	13
Otitis	2 (1.0)			2 (1.0)	1 (0.5)	4	1 (0.7)			1 (0.7)	1 (0.7)	2
Ophthalmopathy	1 (0.5)	1 (0.5)				1	1 (0.7)	1 (0.7)				1
Gastrointestinal Illness	5 (2.5)	6 (3.0)	1 (0.5)	1 (0.5)	1 (0.5)	11	4 (2.8)	5 (3.5)	1 (0.7)		1 (0.7)	8
Anorexia	7 (3.6)	1 (0.5)		5 (2.6)		13	4 (2.8)			4 (2.8)		8
Persons with Complaints:	35 (17.8)	18 (9.1)	7 (3.6)	16 (8.2)	7 (3.6)	60	23 (16.3)	14 (9.9)	4 (2.8)	10 (7.1)	5 (3.5)	43
Persons with No Complaints:	162 (82.2)	179 (90.9)	190 (96.4)	180 (91.8)	188 (96.4)	137	118 (83.7)	127 (90.1)	137 (97.2)	131 (92.9)	136 (96.5)	98
Negative Physician Surveillance				1	2							

MEMO

To File Location Date 2/2/78
 From T. Schofield Location
 Subject Statistical Analysis - Study #442

Analysis of variance was conducted on post titers of children who were initially seronegative to rubella who received rubella vaccine, lot #579 (Group 1), combined measles-mumps-rubella vaccine, lot #621 (Group 2), and combined measles-rubella vaccine, lot #622 (Group 3).

No significant difference exists among the three groups. Geometric mean titers were:

<u>Vaccine</u>	<u>GMT</u>
Rubella	150.5
MMR	143.4
MR	155.5

There is no significant difference in conversion rate among these three groups.

T.S.
 T.S.



Program: Study #470 - To evaluate and compare clinical and immunological responses to two rubella vaccines, administered alone and in combination with measles virus vaccine.

Vaccine: Combined live measles-rubella (RA 27/3) virus vaccine
Lot #662/C-D764

Combined live measles-rubella (HPV-77) virus vaccine
M-R-VAX

Live attenuated RA 27/3 rubella virus vaccine
Lot #579/C-D418
Lot #60664/C-E668

Responsible Clinical Investigator:

Louis Z. Cooper, M.D.
Director, Pediatric Service
The Roosevelt Hospital
428 West 59th Street
New York, New York 10019

Study Location: New York, New York

Date Study Initiated: June 25, 1976

Date Study Completed: In Progress

Study Procedure:

Fifty-four children, 11 months to 18 years of age, have been included in the study thus far. Thirty-six received a 0.5 ml subcutaneous dose of combined live measles-rubella virus vaccine; eighteen received a 0.5 ml subcutaneous dose of live attenuated RA 27/3 rubella virus vaccine. Blood samples were obtained immediately prior to vaccination and six weeks after vaccination from a sample of the population. Each child was followed 6 weeks for clinical complaints. The study continues in progress.

Addendum #1Clinical Protocol - Study #470Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Purpose of

Addendum:

To permit vaccination with monovalent RA 27/3 or HPV-77 duck rubella virus vaccines.

Vaccines:

1. Combined live measles-rubella (RA 27/3) virus vaccine
Lot #622/C-D764

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water without preservative.

2. Combined live measles-rubella (HPV-77 duck embryo) virus vaccine
Lot #0619W

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water without preservative.

3. Live HPV-77 duck embryo rubella virus vaccine
Lot #0406W

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water without preservative.

4. Live RA 27/3 rubella virus vaccine
Lot #60640/C-E668

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water without preservative.

Addendum #1
 Clinical Protocol - Study #470
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Vaccines: CAUTION: Both combined vaccines and the HPV-77 duck rubella virus vaccine contain egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. All of the vaccines contain neomycin and should not be given to persons sensitive to neomycin. Persons with leukemia or other immunologic disorder and persons receiving immunosuppressive drugs should not be vaccinated. The vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of children 1 to 6 years old having negative histories for vaccination and illness caused by measles and/or rubella. Children will receive one of the four vaccines as follows:

<u>Group</u>	<u>Vaccine</u>	<u>No. of Children</u>
1	Measles-rubella (RA 27/3)	Up to 500
2	Measles-rubella (HPV-77 duck)	Up to 500
3	HPV-77 duck rubella	Up to 200
4	RA 27/3 rubella	Up to 200

Informed written consent will be obtained from a parent or guardian of each child participating in the study.

Each child will receive a single 0.5 ml subcutaneous injection of one of the four vaccines.

Bleeding samples (10-15 ml) will be obtained from approximately one-third of the study participants. Samples will be drawn immediately before and 6-8 weeks following vaccination.

Each child will be followed clinically for 42 days after vaccination. All local and systemic complaints will be recorded on the case report form.

Addendum #1

Clinical Protocol - Study #470

Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Schedule:

Time	Vaccination and Follow-Up (All Children)	Bleeding (Approx. 1/3 of Children)
Day 0	Vaccinate 0.5 ml, subcutaneously.	10-15 ml
Days 0-42	Clinical follow-up for local and systemic reactions.	—
Week 6-8	—	10-15 ml

Laboratory: Remove serum from clot aseptically and store frozen at -20°C.

Serology: Circulating levels of measles and rubella antibodies before and after vaccination will be determined by hemagglutination-inhibition test.

Clinical

Form: Attached.

Adverse

Reactions: Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.

Unused

Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.



M. R. Hilleman, Ph.D.

Clinical Protocol - Study #470Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Purpose: To compare antibody and clinical responses to combined live measles-rubella virus vaccine containing the RA 27/3 rubella virus strain or the HPV-77 duck rubella virus strain.

Vaccine: 1. Combined live measles-rubella (RA 27/3) virus vaccine
Lot #622 or Lot #623

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in two-dose vials. Each vial of vaccine should be rehydrated with 1.2 ml of sterile, pyrogen-free distilled water.

2. Combined live measles-rubella (HPV-77 duck) virus vaccine
Lot #2412T

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial of vaccine should be rehydrated with 0.7 ml of sterile, pyrogen-free distilled water.

CAUTION: Both vaccines contain egg protein and should not be given to persons with known sensitivity to chicken or duck, chicken or duck eggs or feathers. The vaccines also contain neomycin and should not be given to persons with sensitivity to neomycin. Persons with leukemia or other immunologic disorders or persons receiving immunosuppressive drugs should not be vaccinated. The vaccines should not be given to persons with any febrile respiratory illness or other active febrile infection.

Keep dried vaccines stored at -20°C.

Keep dried vaccines at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of children 1 to 6 years old having negative histories for vaccination and illness caused by measles and rubella. Children will be randomly assigned to receive one of the two vaccines as follows:

<u>Group</u>	<u>Vaccine</u>	<u>No. of Children</u>
1	measles-rubella (RA 27/3)	up to 500 children
2	measles-rubella (HPV-77 duck)	up to 500 children

Clinical Protocol -
Study #470

-2-

Informed written consent will be obtained from each child's parent or guardian prior to participating in the study.

Each child will receive a single 0.5 ml subcutaneous injection of one of the two combined live measles-rubella virus vaccines.

Bleeding samples (10-15 ml) will be obtained from approximately one-third of the study participants. They will be bled immediately prior to vaccination and 6-8 weeks following vaccination.

Each child will be followed clinically for 42 days after vaccination. All local and systemic complaints will be recorded on the case report form.

Schedule:

Time	Vaccination and Follow-up (All Children)	Bleeding (Approx. 1/3 of Children)
Day 0	Vaccinate 0.5 ml, subcutaneously.	10-15 ml
Days 0-42	Clinical follow-up for local and systemic reactions.	--
Week 6-8	--	10-15 ml

Laboratory: Remove serum from clot aseptically and store frozen at -20°C.

Serology: Circulating levels of measles and rubella antibodies before and after vaccination will be determined by hemagglutination-inhibition test.

Clinical Form: Attached.

Adverse Reactions: Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Allen F. Woodhour, telephone (215) 699-5311, Ext. 5588.

Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pa. 19486.



M. R. Hilleman, Ph.D.

MEASLES - RUBELLA VACCINATION

Study No. (1-3)

Case No. (1-9)

CT 3	Name	Sex (40) M F	Birthdate (20-41) mo day yr			(25-47)
Address						
Indicate if this child:						
<input type="checkbox"/> had disease		Did child develop unusual disease 1 = YES 2 = NO				
<input type="checkbox"/> been vaccinated		Date of onset _____				
<input type="checkbox"/> been exposed		Comments _____				
Date of exposure _____		Diagnosed by _____				
(48) <input type="checkbox"/> Vaccinee <input type="checkbox"/> Control		Date of Vaccination		Bleeding Dates: _____		
Lot No. (49-51)		(52-57)		(58-62)		
				(70-75)		

CT 3	DAY	DATE	Temperature		Malaise	Anorexia	Gastrointestinal	Irritability	Headache	Upper Respiratory	Otitis	Conjunctivitis	Lymphadenopathy	Local Reaction*	Erythema	Rash	Subcutis (size) itch	Arthralgia	Arthritis	*Specify (Type, Location)
			Oral	Rectal																
			24		16	25	03	18	14	01	03	06	03	12	50	51	11	32		
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	1																			
	2																			
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Please return completed forms to: (Return PINK copy for your files)
 M. R. HILLMAN, PhD, DSc
 MERCK SHARP & DOHME RESEARCH LABORATORIES
 WEST POINT, PENNSYLVANIA, 19380, U.S.A.

Physician's Signature _____ Date _____
 Physician's Name (Type or Print) _____

Table 1

Serological Findings Among Children Who Received Combined Live
Measles-Rubella (RA 27/3) Virus Vaccine, Lot #622/C-D764 (Study #470)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:		Initially Seropositive to:
			Measles-Rubella		
			Conversions/Total		Measles and Rubella
Measles	Rubella				
Not Given	1	1			1
(Months)					
14	4	1	1/1	1/1	
15	3	1	1/1	1/1	
16	3	0			
17	1	1	1/1	1/1	
18	1	1	1/1	1/1	
(Years)					
2	6	3	3/3	3/3	
4	2	2	1/1	1/1	1
5	1	1	1/1	1/1	
6	1	1	1/1	1/1	
Total	23	12	10/10	10/10	2
Mean Age:	2.0 Years		(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
10/10	10/10
(100%)	(100%)

5/18/78

Table 2

Serological Findings Among Children Who Received
 Combined Live Measles-Rubella (HPV-77) Virus Vaccine, M-R-VAX (Study #470)

Age	Total No. Vacc.	No. Serol. Tested	Initially Seronegative to:			Initially Seropositive to:	
			Measles-Rubella		Measles Only		Rubella Only
			Conversions/Total		Conversions/		Conversions/
			Measles	Rubella	Total	Total	Measles and Rubella
(Months)							
11	1	0					
14	2	0					
15	2	2	2/2	2/2			
16	2	2	1/1	1/1	1/1		
21	1	1				1/1	
(Years)							
4	1	1			1/1		
5	1	1	1/1	1/1			
7	1	1	1/1	1/1			
9	1	1					1
18	1	1	1/1	1/1			
Total	13	10	6/6	6/6	2/2	1/1	1
Mean Age:	4.1 Years.						

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
8/8	7/7
(100%)	(100%)

10/6/77

Table 3

Distribution of Fold Rises of Hemagglutination Inhibition Antibody Titers Among Children Who Received Live Attenuated RA 27/3 Rubella Virus Vaccine, Lot #579/C-D418 (Study #470)

Age (Years)	No. Vacc.	No. Serol. Tested	Initially Seropositive	Initially Seronegative					
			Total	Paired Sera			Pre-Vacc. Sera Only	Total	
				No. Conv.	No. Fail.	Total			Conv. Rate
1	6	0							
2	2	2		2		2	2/2		2
4	1	1		1		1	1/1		1
5	1	1						1	1
Total	10	4	0	3	0	3	100%	1	4
Mean Age = 2.1 Years									

4/3/78

Table 4

Distribution of Fold Rises of Hemagglutination Inhibition Antibody Titers Among Children Who Received Live Attenuated RA 27/3 Rubella Virus Vaccine, Lot #60664/C-E668 (Study #470)

Age (Years)	No. Vacc.	No. Serol. Tested	Initially Seropositive		Initially Seronegative
			Paired Sera		Total
			>4x Rise	Total	
1	7	0			
5	1	1	1	1	
Total	8	1	1	1	0
Mean Age: 1.8 Years					

4/3/78

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles and Rubella, Who Received Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #622/C-D764 (Study #470)

Measles (HI)	
Post-Titer Distribution	Number of Children
10	1
20	1
40	2
80	5
160	-
>320	1
Total 10 Geometric Mean Titer: >56.6	

Rubella (HI)	
Post-Titer Distribution	Number of Children
128	3
256	3
>512	4
Total 10 Geometric Mean Titer: >274.4	

5/18/78

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles and Rubella, Who Received Combined Live Measles-Rubella (HPV-77) Virus Vaccine, M-R-VAX (Study #470)

Measles (HI)	
Post Titer Distribution	Number of Children
20	1
40	2
80	1
160	1
>320	1
Total	6
Geometric Mean Titer: <u>>71.3</u>	

Rubella (HI)	
Post Titer Distribution	Number of Children
128	2
256	1
>512	3
Total	6
Geometric Mean Titer: <u>>287.3</u>	

10/6/77

Table 7

Distribution of Post-Vaccination Antibody Titers Among Initially Seronegative Children Who Received Live Attenuated RA 27/3 Rubella Virus Vaccine, Lot #579/C-D418 (Study #470)

Rubella (HI)	
Post-Titer Distribution	Number of Children
256	1
≥ 512	2
Total	3
Geometric Mean Titer:	≥ 406.4

1/5/78

STUDY #470

Thus far, two children in the study have exhibited clinical complaints:

CASE NO. - (b) (6)
AGE - 4 Years
VACCINE - Measles-Rubella (RA 27/3)
CLINICAL COMPLAINT - Rubella-Like Rash, Days 2-3
SEROLOGY -
 Rubella HI 32 >512
 Measles HI >320 160

CASE NO. - (b) (6)
AGE - 15 Months
VACCINE - Measles-Rubella (RA 27/3)
CLINICAL COMPLAINT - Upper Respiratory Illness, Day 3
SEROLOGY -
 Rubella HI NS 128
 Measles HI NS 20

1/5/78

Reference No. 3

Program: Study #512 - To measure antibody and clinical responses to three consecutive lots of combined measles-rubella virus vaccine.

Vaccine: Combined live measles-rubella (RA 27/3) virus vaccine, lyophilized,

Lot #62343/C-F021

Lot #62344/C-F022

Lot #62345/C-F023

Responsible Clinical Investigator:

Victor M. Villarejos, M.D.
Director
Louisiana State University
International Center for Medical
Research and Training
Apartado 10.155
San Jose, Costa Rica

Study Location: Nicaragua

Date Study Initiated: October 11, 1977

Date Study Completed: November 26, 1977

Study Procedure:

One hundred seventy-five children, 10 months to 9 years of age were included in the study. Each received a 0.5 ml dose of combined live measles-rubella virus vaccine. Blood samples were obtained on day of vaccination and 6 weeks after vaccination. Each child was followed 6 weeks for clinical complaints.

Clinical Protocol - Study #512Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Program: Combined live measles-rubella virus vaccine

Purpose: To measure antibody and clinical responses to three consecutive lots of vaccine.

Vaccine: Combined live measles-rubella virus vaccine, lyophilized,
Lot no. 62343/C-F021
Lot no. 62344/C-F022
Lot no. 62345/C-F023

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water which is supplied in prefilled syringes.

CAUTION: The vaccine should not be given to persons with known sensitivity to neomycin, chicken, eggs or feathers. Persons with leukemia or other immunologic disorder and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccine should not be given to persons with a febrile respiratory illness or other active febrile infection.

Keep dried vaccine stored at -20°C until used.

Keep dried vaccine at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of up to 150 children with a negative history for vaccination and illness caused by measles and rubella viruses. The children should range from 1 to 6 years of age.

Informed written consent will be obtained from a parent or guardian of each child who participates in the study.

Each child will receive a 0.5 ml subcutaneous injection of one of the three vaccine lots.

Bleeding samples (10-15 ml) will be obtained from each child immediately before and 6 weeks after vaccination.

Clinical Protocol - Study #512
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Procedure: (continued) Each child will be followed clinically for local and systemic complaints occurring within 6 weeks after vaccination. Observations should include special notation for rash, nodes, arthralgia, arthritis, fever, malaise and anorexia. All complaints should be recorded on the case report form.

Schedule:

Time	Action - All Persons
Day 0	Bleed 10-15 ml Vaccinate 0.5 ml, subcutaneously
Days 0-42	Clinical follow-up for local and systemic complaints
Week 6	Bleed 10-15 ml

Laboratory: Remove serum from clot aseptically and store frozen at -20°C until shipped. It is imperative that sera are sterile to avoid interference with the serologic assay.

Serology: Levels of circulating measles and rubella antibodies will be determined by hemagglutination-inhibition test.

Clinical Forms: Attached.

Adverse

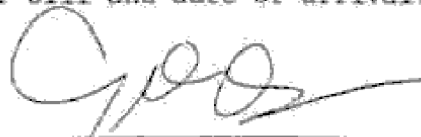
Reactions: Any serious or alarming reaction, including death due to any cause during the investigation, whether related or not related to the test material, must be reported immediately to Merck & Co., Inc., through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext. 5532, or in his absence, Dr. Arlene A. McLean, telephone (215) 699-5311, Ext. 6383.

Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.

Shipping of

Sera & Records:

1. Send sera frozen within insulated containers which are supplied.
2. Send sera and records to Dr. Maurice R. Hilleman, Virus & Cell Biology Research, Merck Sharp & Dohme Research Laboratories, West Point, Pennsylvania 19486.
3. Alert Dr. Hilleman by cable as soon as possible regarding flight number, air bill and date of arrival.



M. R. Hilleman, Ph.D.

Estudio No. _____ (1-3)

OBSERVACIONES CLINICAS

No. Del Caso _____ (5-9)

CT	Nombre completo del niño:	Sexo (35)	Fecha de nacimiento (36-41)			(46-47)
2		M F	dia	mes	año	
Dirección completa de Padre / Guardián:						

VACUNADO NO. de LOTE _____ (49-51) FECHAS de SANGRIA _____ SEROLOGIA _____
 CONTROL (48) FECHA de VACUNACION _____ (52-57) _____ (56-63) _____ (70-75) _____

Dia	Fecha	Temperatura		Malestar	Anorexia	Gastroenteritis	Irritabilidad	Cafea	I.V.R.S.	Otitis	Conjuntivitis	Linfadenopatia	Reaccion Local*	RASH*		Artralgia	Artritis	* Especifique tipo en esta seccion
		Oral	Rectal											Rubelliforme	Morbilliforme			
		24	16	25	08	15	14	01	03	06	05	12	51	52	11	32	OTRAS REACCIONES	
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Al terminar el estudio, devuelva copia blanca y copia amarilla de esta forma a (Retenga copia color de rosa para sus archivos)
M. R. HILLEMANN, PhD, DSc
MERCK SHARP & DOHME RESEARCH LABORATORIES
WEST POINT, PENNSYLVANIA, 19486, U.S.A.

Firma del medico: _____
 Nombre del medico (en letra de molde): _____ Fecha: _____

Table 1

Serological Findings Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #512)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:				Initially Seropositive to: Measles Mumps and Rubella
			Measles-Rubella		Measles Only	Rubella Only	
			Conversions/Total		Conversions/ Total	Conversions/ Total	
			Measles	Rubella			
(Months)							
10	1	1	0/1	1/1			
12	1	1	1/1	1/1			
13	2	2	1/2*	2/2			
16	1	1				1/1	
21	1	1	1/1	1/1			
23	1	1			1/1		
(Years)							
2	7	6	1/2**	2/2		4/4	
3	9	7	3/3	3/3		4/4	
4	6	6	1/1	1/1		5/5	
5	12	11	1/1	1/1	1/1	6/6	3
6	9	9	1/1	1/1		7/7	1
7	7	7	2/2	2/2	1/1	2/2	2
8	2	2				2/2	
9	1	1				1/1	
Total	60	56	12/15	15/15	3/3	32/32	6
Mean Age:	4.4 Years		(80.0%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
15/18	47/47
(83.3%)	(100%)

* Antibody titer QNS,2 by serum neutralization.

** Antibody titer QNS,4 by serum neutralization.

3/23/78

Table 2

Serological Findings Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-F022 (Study #512)

Age (Months)	No. Vacc.	No. Serol. Tested	Initially Seronegative to:			Initially Seropositive to: Measles Mumps and Rubella	
			Measles-Rubella		Measles Only		Rubella Only
			Conversions/Total		Conversions/ Total		Conversions/ Total
			Measles	Rubella			
11	1	1	1/1	1/1			
13	3	3	2/2	2/2		1	
17	1	1				1/1	
22	1	1				1/1	
(Years)							
2	4	2	1/1	1/1		1	
3	9	9	3/3	3/3		2	
4	9	8	3/3	3/3	0/1	1	
5	14	14	1/1	1/1		5	
6	16	14	6/6	6/6	1/1	4	
7	1	1	1/1	1/1			
8	1	1				1/1	
Total	60	55	18/18	18/18	1/2	21/21	
Mean Age:	4.3 Years		(100%)	(100%)	(50.0%)	(100%)	14

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
19/20	39/39
(95.0%)	(100%)

3/23/78

Table 3

Serological Findings Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-F023 (Study #512)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:				Initially Seropositive to: Measles Mumps and Rubella
			Measles-Rubella		Measles Only	Rubella Only	
			Conversions/Total		Conversions/Total	Conversions/Total	
			Measles	Rubella			
(Months)							
13	1	1				1/1	
14	1	1	1/1	1/1			
17	2	2				2/2	
20	1	1	1/1	1/1			
22	1	0					
(Years)							
2	3	3	2/2	2/2		1/1	
3	9	8	3/3	3/3	1/1	4/4	
4	14	12	4/4	4/4	0/1	7/7	
5	12	11	3/3	3/3		6/6	2
6	11	8	2/3	3/3		5/5	
Total	55	47	16/17	17/17	1/2	26/26	2
Mean Age:	4.1 Years		(94.1%)	(100%)	(50.0%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
17/19	43/43
(85.5%)	(100%)

8/11/78

Table 4

Distribution of Post-Vaccination Antibody Titers Among Children
Who Were Initially Seronegative to Measles and Rubella, Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #512)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	3*
5	
10	
20	4
40	6
80	2
Total	15
Geometric Mean Titer:	17.4

Rubella (HI)	
Post-Titer Distribution	Number of Children
32	1
64	
128	1
256	5
>512	8
Total	15
Geometric Mean Titer:	>308.0

3/23/78

* Two cases post-positive by serum neutralization.

Table 5

Distribution of Post-Vaccination Antibody Titers Among Children
Who Were Initially Seronegative to Measles and Rubella, Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-F022 (Study #512)

Measles (HI)	
Post-Titer Distribution	Number of Children
5	1
10	1
20	3
40	8
80	3
160	1
>320	1
Total	18
Geometric Mean Titer:	>40.0

Rubella (HI)	
Post-Titer Distribution	Number of Children
128	1
256	6
>512	11
Total	18
Geometric Mean Titer:	>376.3

3/23/78

Table 6

Distribution of Post-Vaccination Antibody Titers Among Children
 Who Were Initially Seronegative to Measles and Rubella, Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-F023 (Study #512)

Measles (HI)	
Post-Titer Distribution	Number of Children
<5	1
5	
10	
20	2
40	2
80	5
160	5
>320	2
Total	17
Geometric Mean Titer:	>69.9

Rubella (HI)	
Post-Titer Distribution	Number of Children
128	4
256	6
>512	7
Total	17
Geometric Mean Titer:	>289.3

8/11/78

Table 7

Maximum Temperatures Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-8021 (Study #512)

Maximum Temperature (°F, Oral)	Total Vaccinees (60 Children)						Initially Seronegatives (15 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	50 (83.3)	43 (71.7)	45 (75.0)	42 (70.0)	41 (68.3)	20	14 (93.3)	14 (93.3)	11 (73.3)	11 (73.3)	11 (73.3)	8
99 - 100.9	10 (16.7)	17 (28.3)	14 (23.3)	18 (30.0)	19 (31.7)	39	1 (6.7)	1 (6.7)	4 (26.7)	4 (26.7)	4 (26.7)	7
101 - 101.9			1 (1.7)			1						0

3/23/78

Table 8

Maximum Temperatures Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/G-F022 (Study #512)

Maximum Temperature (°F, Oral)	Total Vaccinees (60 Children)					No. with Max. Temp.	Initially Seronegatives (19 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	47 (78.3%)	29 (48.3)	41 (68.3)	35 (58.3)	33 (55.0)	14	15 (78.9)	5 (26.3)	13 (68.4)	11 (57.9)	12 (63.2)	4
99 - 100.9	13 (21.7)	31 (51.7)	19 (31.7)	25 (41.7)	27 (45.0)	46	4 (21.1)	14 (73.7)	6 (31.6)	8 (42.1)	7 (36.8)	15

3/23/78

Table 9

Maximum Temperatures Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62365/C-F023 (Study #512)

Maximum Temperature (°F, Oral)	Total Vaccinees (55 Children)					No. with Max. Temp.	Initially Seronegatives (17 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	44 (80.0)	27 (49.1)	33 (60.0)	33 (60.0)	38 (69.1)	8	12 (70.6)	8 (47.1)	8 (47.1)	11 (64.7)	10 (58.8)	3
99 - 100.9	10 (18.2)	27 (49.1)	22 (40.0)	21 (38.2)	17 (30.9)	44	5 (29.4)	9 (52.9)	9 (52.9)	5 (29.4)	7 (41.2)	13
101 - 101.9	1 (1.8)	1 (1.8)		1 (1.8)		3				1 (5.9)		1

8/11/78

Table 10

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #512)

Clinical Complaint	Total Vaccinees (60 Children)					No. with Complaint	Initially Seronegatives (15 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache			1 (1.7%)			1						0
Irritability				1 (1.7)	1 (1.7)	1						0
Malaise			1 (1.7)			1						0
Upper Respiratory Illness	2 (3.3)	1 (1.7)	2 (3.3)	3 (5.0)	2 (3.3)	7				1 (6.7)		1
Gastrointestinal Illness		2 (3.3)	2 (3.3)	2 (3.3)	2 (3.3)	5		1 (6.7)		1 (6.7)	1 (6.7)	2
Persons with Complaint:	2 (3.3)	3 (5.0)	4 (6.7)	5 (8.3)	4 (6.7)	12	0	1 (6.7)	0	2 (13.3)	1 (6.7)	3
Persons with No Complaint:	58 (96.7)	57 (95.0)	56 (93.3)	55 (91.7)	56 (93.3)	48	15 (100)	14 (93.3)	15 (100)	13 (86.7)	14 (93.3)	12

3/23/78

Table 11

Clinical Complaints Reported Among Children Who Received:
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-P022 (Study #512)

Clinical Complaint	Total Vaccinees (60 Children)					No. with Complaint	Initially Seronegatives (19 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache				1 (1.7%)		1						0
Malaise		1 (1.7)		3 (5.0)	2 (3.3)	4						0
Upper Respiratory Illness	1 (1.7)	3 (5.0)	2 (3.3)	3 (5.0)	3 (5.0)	6	1 (5.3)	1 (5.3)				1
Gastrointestinal Illness	1 (1.7)	3 (5.0)	1 (1.7)		1 (1.7)	4	1 (5.3)	1 (5.3)				1
Persons with Complaint:	2 (3.3)	6 (10.0)	3 (5.0)	3 (5.0)	4 (6.7)	10	2 (10.5)	2 (10.5)	0	0	0	2
Persons with No Complaint:	58 (96.7)	54 (90.0)	57 (95.0)	57 (95.0)	56 (93.3)	50	17 (89.5)	17 (89.5)	19 (100)	19 (100)	19 (100)	17

3/23/78

Table 12

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-F023 (Study #512)

Clinical Complaint	Total Vaccinees (55 Children)					No. with Complaint	Initially Seronegatives (17 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Malaise		1 (1.8%)	2 (3.6)	1 (1.8)		2						0
Anorexia		1 (1.8)	1 (1.8)			1						0
Upper Respiratory Illness	2 (3.6)	3 (5.5)	3 (5.5)	4 (7.3)	2 (3.6)	8			2 (11.8)	1 (5.9)		2
Gastrointestinal Illness	2 (3.6)	3 (5.5)	3 (5.5)		1 (1.8)	6	1 (5.9)	1 (5.9)	1 (5.9)		1 (5.9)	3
Persons with Complaint:	3 (5.5)	6 (10.9)	6 (10.9)	3 (5.5)	2 (3.6)	14	1 (5.9)	1 (5.9)	1 (5.9)	2 (11.8)	2 (11.8)	5
Persons with No Complaint:	52 (94.5)	49 (89.1)	49 (89.1)	52 (94.5)	53 (96.4)	41	16 (94.1)	16 (94.1)	16 (94.1)	15 (88.2)	15 (88.2)	12

8/11/78

MEMO

To File Location Date 8/14/78
From T. Schofield Location
Subject Statistical Analysis - Study #512

No significant differences exist in seroconversion rates for measles and rubella or clinical reaction rates among three lots of combined measles-rubella (RA 27/3) virus vaccine.

Multivariate analysis of variance was performed on post-titer values for children who were initially seronegative to both measles and rubella by the HI test. The log transformation was used. While sample sizes were small, a significant difference exists between the measles HI titers for children who received Lot #62343/C-F021 and children who received Lot #62345/C-F023. No other differences could be determined. Geometric mean titers were:

	<u>Measles</u>	<u>Rubella</u>
Lot #62343/C-F021 (n=15)	17.4	308.0
Lot #62344/C-F022 (n=18)	40.0	376.3
Lot #62345/C-F023 (n=17)	69.9	289.3



T.S.



Program: Study #514 - To measure antibody and clinical responses to three consecutive lots of combined measles-rubella virus vaccine.

Vaccine: Combined live measles-rubella virus vaccine, lyophilized

Lot #62343/C-F021

Lot #62344/C-F022

Lot #62345/C-F023

Responsible Clinical Investigator:

Robert E. Weibel, M.D.
Director, Division of Preventive Medicine
Joseph Stokes, Jr. Research Institute
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, Pennsylvania 19104

Study Locations:

Pediatric Medical Associates, Havertown, Pennsylvania
Lansdale Medical Group, Lansdale, Pennsylvania
Geisinger Medical Center, Danville, Pennsylvania
G. F. Schultheis, Jr., M.D. and W. W. Holm, M.D.,
King of Prussia, Pennsylvania
G. A. Starkweather, M.D., Havertown, Pennsylvania
Children's Clinic of Chester and Vicinity, Chester,
Pennsylvania

Date Study Initiated: September 9, 1977

Date Study Completed: May 13, 1978

Study Procedure:

One hundred sixty-seven children, 13 months to 12 years of age, were included in the study. Each received a 0.5 ml subcutaneous dose of combined live measles-rubella virus vaccine. Blood samples were obtained on day of vaccination and 6 weeks after vaccination. Each child was followed 6 weeks for clinical complaints.

Clinical Protocol - Study #514Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Program: Combined live measles-rubella virus vaccine

Purpose: To measure antibody and clinical responses to three consecutive lots of vaccine.

Vaccine: Combined live measles-rubella virus vaccine, lyophilized,

Lot no. 62343/C-F021

Lot no. 62344/C-F022

Lot no. 62345/C-F023

Vaccine dose is 0.5 ml given subcutaneously.

The vaccine is supplied in single dose vials. Each vial should be reconstituted with 0.7 ml of sterile, pyrogen-free distilled water which is supplied in prefilled syringes.

CAUTION: The vaccine should not be given to persons with known sensitivity to neomycin, chicken, eggs or feathers. Persons with leukemia or other immunologic disorder and persons receiving immunosuppressive drugs should not be vaccinated. Also, the vaccine should not be given to persons with a febrile respiratory illness or other active febrile infection.

Keep dried vaccine stored at -20°C until used.

Keep dried vaccine at 4°C in transport.

Keep reconstituted vaccine on ice. Discard unused vaccine 4 hours after rehydration.

Procedure: The study population will consist of up to 150 children with a negative history for vaccination and illness caused by measles and rubella viruses. The children should range from 1 to 6 years of age.

Informed written consent will be obtained from a parent or guardian of each child who participates in the study.

Each child will receive a 0.5 ml subcutaneous injection of one of the three vaccine lots.

Bleeding samples (10-15 ml) will be obtained from each child immediately before and 6 weeks after vaccination.

Clinical Protocol - Study #514
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine

Procedure: Each child will be followed clinically for local and systemic
 (continued) complaints occurring within 6 weeks after vaccination. Obser-
 vations should include special notation for rash, nodes, arthralgia,
 arthritis, fever, malaise and anorexia. All complaints should be
 recorded on the case report form.

Schedule:

Time	Action - All Persons
Day 0	Bleed 10-15 ml Vaccinate 0.5 ml, subcutaneously
Days 0-42	Clinical follow-up for local and systemic complaints
Week 6	Bleed 10-15 ml

Serology: Levels of circulating measles and rubella antibodies will be
 determined by hemagglutination-inhibition test.

Clinical Forms: Attached.

Adverse

Reactions: Any serious or alarming reaction, including death due to any cause
 during the investigation, whether related or not related to the
 test material, must be reported immediately to Merck & Co., Inc.,
 through Dr. Maurice R. Hilleman, telephone (215) 699-5311, Ext.
 5532, or in his absence, Dr. Arlene A. McLean, telephone (215) 699-5311,
 Ext. 6383.

Unused Vaccine: All unused vaccine should be returned immediately to Merck Sharp &
 Dohme Research Laboratories, West Point, Pennsylvania 19486.



M. R. Hilleman, Ph.D.

SYMPTOM RECORD

RUBELLA STUDY NO. _____

N. _____ (Last) _____ (First) _____ (Middle) CASE NO. _____

DAY	DATE	Temperature		NONE	RUNNY NOSE	SORE THROAT	COUGH	EAR ACHE	SWOLLEN GLANDS	SORE EYES	VOMITING	DIARRHEA	NAUSEA	* RASH	SORE JOINTS	SORE ARM (at shot)*	HEADACHE	ACHINESS	FEVER	LOSS OF APPETITE	* Describe	COMMENTS
		<input type="checkbox"/> Rectal	<input type="checkbox"/> Oral (Check One)																			
INSTRUCTIONS ON REVERSE SIDE																						
0																						
1																						
2																						
3																						
4																						
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If fever or unusual reaction develops, call:

PLEASE RETURN FOR FOLLOW-UP VISIT ON: _____

BE SURE TO BRING THIS RECORD ALONG WITH YOU.

THE JOSEPH STOKES, JR. RESEARCH INSTITUTE
THE CHILDREN'S HOSPITAL OF PHILADELPHIA
UNIVERSITY OF PENNSYLVANIA
34TH & CIVIC CENTER BLVD.
PHILADELPHIA, PA. 19104

ROBERT E. WEIBEL, M.D., DIRECTOR
DIVISION OF PREVENTIVE MEDICINE

(215) EV 7-8000
(215) EV 7-1800

November 10, 1977

Arlene A. McLean, Ph.D.
Director, Biologics Evaluation & Analysis
Merck Sharp & Dohme Research Laboratories
West Point, Pennsylvania 19486

RE: Clinical Protocol - Study #514
Combined Live Measles-Rubella Vaccine

Dear Arlene:

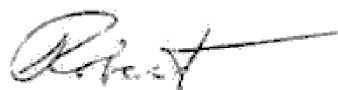
At the conclusion of the first thirty vaccinees (b) (6) at Pediatric Associates it was noted by Dr. Al Carlson that the lot number on the last vial C-F022 did not correspond with the lot required on the work sheet. After a thorough review of the situation it can not be determined when the lot of vaccine not corresponding to the record was given. This information must be considered in the evaluation of all clinical and serologic records from these vaccinees.

The following steps have been taken to prevent the recurrence of this situation:

1. In addition to the color code for each lot, as now used, the required vaccine lot will be placed on the study registration sheet in the required color of the lot.
2. Each lot will be placed in a separate color coded box rather than in a single box with color coded areas as now used.

These changes have been instituted to insure the accuracy of the records.

Sincerely,



Robert E. Weibel, M.D.

REW:ceb

cc: Alfred Carlson, M.D.
Karen Campbell, R.N.

Table 1

Serological Findings Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #514)

Age (Months)	No. Vacc.	No. Serol. Tested	Initially Seronegative to:			Initially Seropositive to:	
			Measles-Rubella		Measles Only	Rubella Only	Measles and Rubella
			Conversions/ Total	Conversions/ Total	Conversions/ Total		
			Measles	Rubella	Total	Total	
13	1	0					
14	8	8	7/8	8/8			
15	17	16	13/13*	13/13	3/3		
16	8	8	8/8	8/8			
17	2	2	2/2	2/2			
18	3	3	2/2	2/2	1/1		
19	1	0					
20	1	1			1/1		
21	1	1				1/1	
23	1	1	1/1	1/1			
(Years)							
2	3	3	1/1	1/1	2/2		
3	1	1				1/1	
Total	47	44	34/35	35/35	7/7	2/2	0
Mean Age:	1.4 Years		(97.1%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

Measles	Rubella
41/42	37/37
(97.6%)	(100%)

* One sample pair tested by serum neutralization.

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Table 2

Serological Findings Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-F022 (Study #514)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:			Initially Seropositive to:	
			Measles-Rubella		Measles Only		Rubella Only
			Conversions/Total		Conversions/Total		Conversions/Total
			Measles	Rubella	Total	Total	Measles and Rubella
(Months)							
14	5	5	5/5	5/5			
15	16	16	12/12	12/12	3/4		
16	6	4	2/2	2/2	2/2		
17	5	4	2/2	2/2	1/2		
18	5	5	4/4	4/4	1/1		
19	1	1	1/1	1/1			
21	2	1	1/1	1/1			
(Years)							
2	2	1			1/1		
4	1	0					
8	1	1				1/1	
12	1	1				1/1	
Total	45	39	27/27	27/27	8/10	2/2	0
Mean Age:	1.8 Years		(100%)	(100%)	(80.0%)	(100%)	

Overall Conversion Rates

Measles	Rubella
35/37	29/29
(94.6%)	(100%)

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Table 3

Serological Findings Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-F023 (Study #514)

Age	No. Vacc.	No. Serol. Tested	Initially Seronegative to:				Initially Seropositive to: Measles and Rubella
			Measles-Rubella		Measles Only	Rubella Only	
			Conversions/Total		Conversions/Total	Conversions/Total	
			Measles	Rubella	Total	Total	
(Months)							
13	1	1	1/1	1/1			
14	7	6	5/5	5/5	1/1		
15	13	13	11/11	11/11	2/2		
16	14	14	9/9	9/9	4/4	1/1	
17	4	4	3/3	3/3	1/1		
18	2	2	1/1	1/1	1/1		
21	1	1	1/1	1/1			
(Years)							
2	2	1	1/1	1/1			
4	1	1	1/1	1/1			
Total	45	43	33/33	33/33	9/9	1/1	0
Mean Age:	1.4 Years		(100%)	(100%)	(100%)	(100%)	

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
42/42	34/34
(100%)	(100%)

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Table 4

Serological Findings Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot # Unknown (Study #514)

Age (Months)	No. Vacc.	No. Serol. Tested	Initially Seronegative to:				Initially Seropositive to: Measles and Rubella
			Measles-Rubella		Measles Only	Rubella Only	
			Conversions/Total		Conversions/ Total	Conversions/ Total	
			Measles	Rubella			
13	2	2	1/2	2/2			
14	5	5	5/5	5/5			
15	18	18	16/17*	17/17	1/1		
17	1	1	1/1	1/1			
18	1	1	1/1	1/1			
(Years)							
2	1	1				1/1	
7	1	1	1/1	1/1			
10	1	1	1/1	1/1			
Total	30	30	26/28	28/28	1/1	1/1	
Mean Age:	1.7 Years		(92.9%)	(100%)	(100%)	(100%)	0

Overall Conversion Rates

<u>Measles</u>	<u>Rubella</u>
27/29	29/29
(93.1%)	(100%)

* One sample pair tested by serum neutralization.

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Table 5

Distribution of Post-Vaccination Antibody Titers Among Children Who Were Initially Seronegative to Measles and Rubella, Who Received Combined Live Measles-Rubella (RA 27/3) Virus Vaccine (Study #514)

	Post-Titer Distribution	Number of Children			
		Lot #62343/C-F021	Lot #62344/C-F022	Lot #62345/C-F023	Lot # Unknown
Measles (HI)	<5	1			2
	5				1
	10				1
	20		2	1	2
	40	12	10	4	5
	80	9	6	12	8
	160	6	5	9	5
	≥320	6	4	7	3
	Total	34	27	33	27
	Geometric Mean Titer:	≥79.5*	≥78.0	≥114.3	≥50.9*
Rubella (HI)	64	1		1	1
	128	5	2		4
	256	12	9	7	2
	≥512	17	16	25	21
		Total	35	27	33
	Geometric Mean Titer:	≥312.1	≥366.7	≥415.0	≥371.1

* One titer determined by serum neutralization not included in calculation of G.M.T.

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Table 6

Maximum Temperatures Reported Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #514)

Maximum Temperature (°F, Oral)	Total Vaccinees (47 Children)					No. with Max. Temp.	Initially Seronegatives (38 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	30 (66.7%)	15 (33.3)	30 (66.7)	28 (63.6)	22 (50.0)	12	27 (75.0)	13 (36.1)	25 (69.4)	27 (75.0)	20 (55.6)	11
99 - 100.9	13 (28.9)	22 (48.9)	13 (28.9)	14 (31.8)	15 (34.1)	14	8 (22.2)	17 (47.2)	9 (25.0)	7 (19.4)	9 (25.0)	9
101 - 102.9		7 (15.6)	2 (4.4)	3 (2.3)	5 (11.4)	15		5 (13.9)	2 (5.6)	1 (2.8)	5 (13.9)	13
103 - 104.0	2 (4.4)	1 (2.2)		1 (2.3)	2 (4.5)	4	1 (2.8)	1 (2.8)		1 (2.8)	2 (5.6)	3
Not Taken	2	2	2	3	3	2	2	2	2	2	2	2

Case #	Max. Temp.	Days	Clinical Complaint	Serology	
				Measles	Rubella
(b) (6)	102.2	35-38	Upper Respiratory Illness, Gastrointestinal Illness, Nonspecific Rash, Teething	<5	80 <8 >512
	102.0	9-11	Upper Respiratory Illness, Otitis, Anorexia	<5	160 <8 >512
	103.0	10	None	<5	80 <8 >512
	103.4	29-31	Upper Respiratory Illness, Nonspecific Rash		
	102.0	13-14	Teething	<5	80 <8 256
	103.0	3-6	Upper Respiratory Illness	<5	<5 <8 256
	102.0	41-42	Upper Respiratory Illness, Irritability, Anorexia, Myalgia	<5	40 <8 >512
	104.0	7-10	Measles-Like Rash	<5	40 <8 >512
	103.0	32-36	Lower Respiratory Illness, Gastrointestinal Illness		
	102.0	8-12	Upper Respiratory Illness, Lymphadenopathy	<5	>320 <8 >512
	103.2	25-35	Irritable, Viral Infection, Non-Specific Rash, Anorexia	<5	>320 <8 256
	103.0	0-4	Non-Specific Rash, Anorexia	<5	>320 8 64

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Table 7

Maximum Temperatures Reported Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-F022 (Study #514)

Maximum Temperature (°F, Oral)	Total Vaccinees (45 Children)						Initially Seronegatives (32 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	21 (48.8%)	13 (30.2)	28 (65.1)	25 (59.5)	22 (52.4)	9	17 (56.7)	10 (33.3)	21 (70.0)	18 (62.1)	15 (51.7)	7
99 - 100.9	21 (48.8)	21 (48.8)	14 (32.6)	12 (28.6)	18 (42.9)	20	13 (43.3)	13 (43.3)	9 (30.0)	8 (27.6)	12 (41.4)	14
101 - 102.9	1 (2.3)	8 (18.6)	1 (2.3)	2 (4.8)	2 (4.8)	10		6 (20.0)		2 (6.9)	2 (6.9)	7
103 - 104.6		1 (2.3)		3 (7.1)		4		1 (3.3)		1 (3.4)		2
Not Taken	2	2	2	3	3	2	2	2	2	3	3	2

Case #	Max. Temp.	Days	Clinical Complaint	Serology	
				Measles	Rubella
(b) (6)	102.7	5-9	Upper Respiratory Illness, Ophthalmopathy, Gastrointestinal Illness	<5	160 32 >512
	103.0	18-19	Upper Respiratory Illness		
	104.6	22-25	Upper Respiratory Illness, Gastrointestinal Illness	<5	160 8 >512
	103.0	18-23	Upper Respiratory Illness, Gastrointestinal Illness, Nonspecific Rash, Anorexia	<5	40 <8 >512
	103.0	10-11	Upper Respiratory Illness	<5	40 <8 >512
	102.2	10	Upper Respiratory Illness, Gastrointestinal Illness, Irritability, Anorexia	<5	40 >512 >512
	102.0	4-6	Upper Respiratory Illness, Myalgia	<5	<5 128 >512
	102.0	3-10	Irritability	<5	>320 <8 >512

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Table 8

Maximum Temperatures Reported Among Children Who Received
 Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-P023 (Study #514)

Maximum Temperature ("F, Oral)	Total Vaccinees (45 Children)						Initially Seronegatives (33 Children)					
	Days Post Vaccination					No. with Max. Temp.	Days Post Vaccination					No. with Max. Temp.
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	26 (59.1)	14 (31.8)	25 (56.8)	21 (47.7)	24 (54.5)	13	22 (66.7)	11 (33.3)	19 (57.6)	17 (51.5)	18 (54.5)	10
99 - 100.9	16 (36.4)	17 (38.6)	16 (36.4)	19 (43.2)	15 (34.1)	13	11 (33.3)	13 (39.4)	11 (33.3)	13 (39.4)	10 (30.3)	10
101 - 102.9	1 (2.3)	5 (11.4)	2 (4.5)	2 (4.5)	4 (9.1)	13		2 (6.1)	2 (6.1)	1 (3.0)	4 (12.1)	8
103 - 104.8		4 (9.1)				4		4 (12.1)				4
105.0		1 (2.3)				1		1 (3.0)				1
Fever - No Temperature	1	3	1	2	1		2	1	2	1		
Not Taken	1	1	1	1	1							

Case #	Max. Temp.	Days	Clinical Complaint	Serology		
				Measles	Rubella	
(b) (6)	102.2	39	Upper Respiratory Illness, Gastrointestinal Illness, Anorexia	<5	160	<8 >512
	102.0	5-11	None	<5	40	32 >512
	105.0	5-7	Upper Respiratory Illness, Otitis, Anorexia	<5	160	<8 >256
	104.2	10-11	Upper Respiratory Illness, Gastrointestinal Illness, Headache	<5	160	<8 >512
	104.8	4-9	Upper Respiratory Illness, Otitis, Irritable, Anorexia	<5	>320	<8 >256
	104.0	8-14	Upper Respiratory Illness, Gastrointestinal Illness, Anorexia	<5	>320	<8 >512
	102.4	1	None	<5	80	8 >256
	104.0	5-7	Upper Respiratory Illness, Anorexia	<5	160	<8 >512
	102.0	7-11	Gastrointestinal Illness, Measles-like Rash	<5	80	<8 >512

Table 9

Maximum Temperatures Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot # Unknown (Study #514)

Maximum Temperature (°F, Oral)	Total Vaccinees (30 Children)					No. with Max. Temp.	Initially Seronegatives (28 Children)					No. with Max. Temp.
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
<99	20 (66.7%)	18 (60.0)	22 (73.3)	19 (63.3)	16 (53.3)	11	18 (64.3)	16 (57.1)	20 (71.4)	17 (60.7)	15 (53.6)	10
99 - 100.9	10 (33.3)	6 (20.0)	7 (23.3)	9 (30.0)	10 (33.3)	9	10 (35.7)	6 (21.4)	7 (25.0)	9 (32.1)	9 (32.1)	8
101 - 102.9		4 (13.3)	1 (3.3)	1 (3.3)	3 (10.0)	7		4 (14.3)	1 (3.6)	1 (3.6)	3 (10.7)	7
103 - 104.0		2 (6.7)		1 (3.3)	1 (3.3)	3		2 (7.1)		1 (3.6)	1 (3.6)	3

Case # (b) (6)	Max. Temp.	Days	Clinical Complaint	Serology	
				Measles	Rubella
	103.4	21-22	Upper Respiratory Illness, Otitis, Gastrointestinal Illness, Anorexia	<5	160 <8 >512
	102.1	16-17	Upper Respiratory Illness	<5	10 <8 128
	104.0	6-10	Measles-Like Rash	<5	40 <8 >512
	103.0	32-36	Bronchitis, Gastrointestinal Illness		
	103.0	7-12	Gastrointestinal Illness, Measles-Like Rash	<5	40 <8 >512
	102.0	10-11	Gastrointestinal Illness, Anorexia	<5	80 <8 256

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Table 10

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62343/C-F021 (Study #514)

Clinical Complaint	Total Vaccinees (47 Children)					No. with Complaint	Initially Seronegatives (38 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (4.3%)					2	2 (5.4)					2
Soreness	1					1	1					1
Erythema and Soreness	1					1	1					1
Systemic:												
Lymphadenopathy	1 (2.2)	1 (2.2)				2		1 (2.7)				1
Measles-Like Rash		2 (4.3)				2		1 (2.7)				1
Irritability	5 (10.9)	5 (10.9)	1 (2.2)	3 (6.7)	2 (4.4)	10	5 (13.5)	3 (8.1)		2 (5.4)	1 (2.7)	8
Anorexia	9 (19.6)	13 (28.3)	6 (13.0)	7 (15.6)	8 (17.8)	22	8 (21.6)	12 (32.4)	5 (13.5)	6 (16.2)	5 (13.5)	18
Disturbed Sleep		1 (2.2)		2 (4.4)	2 (4.4)	3		1 (2.7)		2 (5.4)	2 (5.4)	3
Fatigue	2 (4.3)	2 (4.3)	1 (2.2)			4	2 (5.4)	1 (2.7)				3
Myalgia		1 (2.2)	1 (2.2)		1 (2.2)	1		1 (2.7)	1 (2.7)		1 (2.7)	1
Upper Respiratory Illness	19 (41.3)	22 (47.8)	20 (43.5)	16 (35.6)	18 (40.0)	35	16 (43.2)	19 (51.4)	17 (45.9)	13 (35.1)	14 (37.8)	28
Otitis		2 (4.3)	3 (6.5)	1 (2.2)		4		2 (5.4)	3 (8.1)	1 (2.7)		4
Ophthalmopathy	1 (2.2)		2 (4.3)	2 (4.4)		3	1 (2.7)		2 (5.4)	2 (5.4)		3
Gastrointestinal Illness	7 (15.2)	6 (13.0)	4 (8.7)	7 (15.6)	9 (20.0)	19	7 (18.9)	5 (13.5)	3 (8.1)	7 (18.9)	7 (18.9)	15
Nonspecific Rash	4 (8.7)	3 (6.5)	1 (2.2)	4 (8.9)	5 (11.1)	9	3 (8.1)	2 (5.4)	1 (2.7)	4 (10.8)	5 (13.5)	7
Other*	2 (4.3)				1 (2.2)	3	2 (5.4)				1 (2.7)	3
Viral Infection					2 (4.4)	2					1 (2.7)	1
Teething		2 (4.3)	1 (2.2)	3 (6.7)	5 (11.1)	8		2 (5.4)	1 (2.7)	3 (8.1)	5 (13.5)	8
Persons with Complaint:	27 (58.7)	29 (63.0)	25 (54.3)	23 (51.1)	23 (51.1)	40	23 (62.2)	24 (64.9)	20 (54.1)	19 (51.4)	17 (45.9)	32
Persons with No Complaint:	19 (41.3)	17 (37.0)	21 (45.7)	22 (48.9)	22 (48.9)	6	14 (37.8)	13 (35.1)	17 (45.9)	18 (48.6)	20 (54.1)	5
Negative Surveillance	1	1	1	2	2	1	1	1	1	1	1	1

*Includes nosebleed, bruise from venipuncture, and ulcers on tongue.

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Table 11

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62344/C-P022 (Study #514)

Clinical Complaint	Total Vaccinees (45 Children)					No. with Complaint	Initially Seronegatives (32 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Lymphadenopathy		1 (2.3%)				1		1 (3.3)				1
Measles-Like Rash		3 (7.0)	2 (4.7)			4		2 (6.7)	2 (6.7)			3
Headache	1 (2.3)	3 (7.0)	1 (2.3)		1 (2.3)	4		2 (6.7)				2
Irritability	1 (2.3)	2 (4.7)	1 (2.3)			3	1 (3.3)	1 (3.3)				2
Anorexia	3 (7.0)	4 (9.3)	4 (9.3)	3 (7.0)	3 (7.0)	14	3 (10.0)	2 (6.7)	3 (10.0)	3 (10.0)	1 (3.3)	9
Fatigue	2 (4.7)		1 (2.3)			2	2 (6.7)		1 (3.3)			2
Myalgia	2 (4.7)	3 (7.0)	2 (4.7)	1 (2.3)	1 (2.3)	5	1 (3.3)	2 (6.7)	1 (3.3)	1 (3.3)		3
Upper Respiratory Illness	20 (46.5)	17 (39.5)	16 (37.2)	18 (41.9)	14 (32.6)	32	11 (36.7)	10 (33.3)	11 (36.7)	13 (43.3)	10 (33.3)	21
Otitis		1 (2.3)	1 (2.3)		2 (4.7)	3		1 (3.3)	1 (3.3)		2 (6.7)	3
Ophthalmopathy	2 (4.7)	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	6	2 (6.7)	3 (10.0)	2 (6.7)	1 (3.3)	1 (3.3)	5
Gastrointestinal Illness	5 (11.6)	12 (27.9)	7 (16.3)	10 (23.3)	7 (16.3)	21	3 (10.0)	7 (23.3)	4 (13.3)	7 (23.3)	3 (10.0)	13
Nonspecific Rash	4 (9.3)	7 (16.3)	7 (16.3)	9 (20.9)	5 (11.6)	13	1 (3.3)	3 (10.0)	4 (13.3)	6 (20.0)	2 (6.7)	8
Varicella					1 (2.3)	1						0
Other*	1 (2.3)		1 (2.3)			2			1 (3.3)			1
Teething	2 (4.7)	3 (7.0)	2 (4.7)	1 (2.3)	3 (7.0)	8	1 (3.3)	2 (6.7)	1 (3.3)	1 (3.3)	2 (6.7)	5
Persons with Complaint:	25 (58.1)	30 (69.8)	23 (53.5)	21 (48.8)	20 (46.5)	35	15 (50.0)	19 (63.3)	15 (50.0)	15 (50.0)	12 (40.0)	23
Persons with No Complaint:	18 (41.9)	13 (30.2)	20 (46.5)	22 (51.2)	23 (53.5)	8	15 (50.0)	11 (36.7)	15 (50.0)	15 (50.0)	18 (60.0)	7
Negative Surveillance:	2	2	2	2	2	2	2	2	2	2	2	2

* Includes soreness at site of venipuncture and ulcers on tongue.

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Table 12

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot #62345/C-P023 (Study #514)

Clinical Complaint	Total Vaccinees (45 Children)					No. with Complaint	Initially Seronegatives (33 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	1 (2.3)					1	1 (3.0)					1
Soreness	1					1	1					1
Systemic:												
Measles-Like Rash		4 (9.1)	1 (2.3)			4		3 (9.1)	1 (3.0)			3
Headache	1 (2.3)	2 (4.5)	1 (2.3)	2 (4.5)		2	1 (3.0)	2 (6.1)	1 (3.0)	2 (6.1)		2
Irritability	1 (2.3)	2 (4.5)	1 (2.3)		1 (2.3)	4		2 (6.1)	1 (3.0)		1 (3.0)	3
Anorexia	6 (13.6)	11 (25.0)	3 (6.8)	6 (13.6)	9 (20.5)	17	5 (15.2)	9 (27.3)	2 (6.1)	4 (12.1)	6 (18.2)	13
Fatigue		1 (2.3)				1		1 (3.0)				1
Myalgia			1 (2.3)		1 (2.3)	1			1 (3.0)		1 (3.0)	1
Upper-Respiratory Illness	14 (31.8)	25 (56.8)	20 (45.5)	24 (54.5)	19 (43.2)	38	10 (30.3)	19 (57.6)	14 (42.4)	18 (54.5)	13 (39.4)	29
Otitis	1 (2.3)	4 (9.1)	3 (6.8)	2 (4.5)	2 (4.5)	6		3 (9.1)	2 (6.1)	2 (6.1)	1 (3.0)	5
Ophthalmopathy	1 (2.3)	3 (6.8)	1 (2.3)			3	1 (3.0)	1 (3.0)	1 (3.0)			1
Gastrointestinal Illness	7 (15.9)	12 (27.3)	7 (15.9)	5 (11.4)	10 (22.7)	23	5 (15.2)	9 (27.3)	4 (12.1)	3 (9.1)	7 (21.2)	15
Nonspecific Rash	4 (9.1)	5 (11.4)	3 (6.8)	3 (6.8)	3 (6.8)	11	2 (6.1)	3 (9.1)	2 (6.1)	2 (6.1)	3 (9.1)	8
Teething	1 (2.3)	1 (2.3)		2 (4.5)	2 (4.5)	5		1 (3.0)		2 (6.1)	2 (6.1)	4
Persons with Complaint:	22 (50.0)	32 (72.7)	26 (59.1)	27 (61.4)	25 (56.8)	41	16 (48.5)	25 (75.8)	19 (57.6)	21 (63.6)	19 (57.6)	31
Persons with No Complaint:	22 (50.0)	12 (27.3)	18 (40.9)	17 (38.6)	19 (43.2)	3	17 (51.5)	8 (24.2)	14 (42.4)	12 (36.4)	14 (42.4)	2
Negative Surveillance	1	1	1	1	1	1						

6/27/78

Table 13

Clinical Complaints Reported Among Children Who Received
Combined Live Measles-Rubella (RA 27/3) Virus Vaccine, Lot # Unknown (Study #514)

Clinical Complaint	Total Vaccinees (30 Children)						Initially Seronegatives (28 Children)					
	Days Post Vaccination					No. with Complaint	Days Post Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (6.7%)					2	2 (7.1)					2
Erythema	1					1	1					1
Soreness	1					1	1					1
Systemic:												
Lymphadenopathy		1 (3.3)				1		1 (3.6)				1
Measles-Like Rash		4 (13.3)	2 (6.7)			4	4 (14.3)	2 (7.1)				4
Headache		1 (3.3)				1	1 (3.6)					1
Irritability	2 (6.7)	2 (6.7)	1 (3.3)	1 (3.3)	2 (6.7)	4	2 (7.1)	2 (7.1)	1 (3.6)	1 (3.6)	2 (7.1)	4
Anorexia	1 (3.3)	3 (10.0)	2 (6.7)	5 (16.7)	5 (16.7)	9	1 (3.6)	2 (7.1)	2 (7.1)	4 (14.3)	4 (14.3)	8
Fatigue				1 (3.3)	1 (3.3)	1				1 (3.6)	1 (3.6)	1
Upper Respiratory Illness	18 (60.0)	14 (46.7)	11 (36.7)	13 (43.3)	19 (63.3)	26	18 (64.3)	13 (46.4)	11 (39.3)	12 (42.9)	18 (64.3)	24
Lower Respiratory Illness					1 (3.3)	1					1 (3.6)	1
Otitis				1 (3.3)		1				1 (3.6)		1
Ophthalmopathy	1 (3.3)	2 (6.7)	2 (6.7)			3	1 (3.6)	2 (7.1)	2 (7.1)			3
Gastrointestinal Illness	3 (10.0)	6 (20.0)	3 (10.0)	5 (16.7)	5 (16.7)	14	3 (10.7)	5 (17.9)	3 (10.7)	5 (17.9)	5 (17.9)	13
Nonspecific Rash	1 (3.3)	1 (3.3)	1 (3.3)		3 (10.0)	5	1 (3.6)	1 (3.6)	1 (3.6)		3 (10.7)	5
Bell's Palsy				1 (3.3)		1				1 (3.6)		1
Teething	2 (6.7)		3 (10.0)	3 (10.0)	1 (3.3)	7	2 (7.1)		3 (10.7)	3 (10.7)	1 (3.6)	7
Persons with Complaint:	21 (70.0)	20 (66.7)	13 (43.3)	17 (56.7)	22 (73.3)	28	21 (75.0)	18 (64.3)	13 (46.4)	16 (57.1)	20 (71.4)	26
Persons with No Complaint:	9 (30.0)	10 (33.3)	17 (56.7)	13 (43.3)	8 (26.7)	2	7 (25.0)	10 (35.7)	15 (53.6)	12 (42.9)	8 (28.6)	2

MEMO

To File Location Date 8/14/78
From T. Schofield Location
Subject Statistical Analysis - Study #514

Significant differences in seroconversion rates for measles and rubella and clinical reaction rates among vaccinees receiving three lots of combined measles-rubella (RA 27/3) vaccine were investigated. Lots of vaccine were:

Lot #62343/C-F021
Lot #62344/C-F022
Lot #62345/C-F023

No significant differences exist among the three lots for any of these rates.

The groups (lots) were investigated for statistical differences in post-vaccination titer among vaccinees who were initially seronegative to both measles and rubella by the HI test. Multivariate analysis of variance was run in conjunction with the Kruskal-Wallis k-sample test on the individual components. No significant differences could be determined among the three lots of vaccine.



T.S.



Hearing Exhibit 4



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BETHESDA, MARYLAND 20914

Page #1
SEP 15 1978

Our Reference Nos. 76-316, 77-303 and 77-304

Alan Gray, Ph.D.
Merck Sharp & Dohme
Division of Merck and Co., Inc.
West Point, Pennsylvania 19486

Dear Dr. Gray:


This is to inform you that the amendments to your product license applications to include the use of the RA27/3 strain rubella virus grown in human diploid cells have been accepted for manufacture of the following products:

Rubella Virus Vaccine, Live
Measles, Mumps and Rubella Virus Vaccine, Live
Measles and Rubella Virus Vaccine, Live

We agree that the results of stability testing of vaccines prepared with the buffered sorbitol-gelatin diluent support your request for a longer dating period. Accordingly, your license applications for the three products are also amended to include the use of the diluent and a dating period of two years at 2^o-8^o C from date of issue.

Please continue to submit stability data as they become available.

Sincerely yours,

for 
Harry M. Meyer, Jr., M.D.
Director
Bureau of Biologics

Summary No. 1
of
Clinical Investigative Studies
of

Combined Live Measles Virus Vaccine (Moraten Line-ATTENUVAX)
Jeryl Lynn Mumps Virus Vaccine (MUMPSVAX)
RA 27/3 Rubella Virus Vaccine

for Purpose of Support for
a License to Manufacture and Sell.



M. R. Hilleman, Ph.D.

Prepared: April 27, 1978
Merck Institute for Therapeutic Research
West Point, Pennsylvania

Summary of Clinical Tests of Combined Live
Measles-Mumps-Rubella (RA 27/3) Virus Vaccine

Study No.	Investigator	Lot No.	Age		No. Vacc.	Antibody Responses among Triple Seronegatives									Re.
						Measles			Mumps			RA 27/3 Rubella			
			Range	Mean (Yrs.)		No. Conv./ No. Seroneg. (%)	GMT	No. Conv./ No. Seroneg. (%)	GMT	No. Conv./ No. Seroneg. (%)	GMT				
442	Villarejos	621	10m- 7y	3.7	199	23/23 (100)	99	22/23 (96)	7	23/23 (100)	149	1			
443	Weibel	621	11m- 8y	1.7	105	65/69 (94)	56	66/69 (96)	8	69/69 (100)	133	2			
459	Lerman	60664	14m- 4y	1.6	41	13/14 (93)	62	13/14 (93)	17	14/14 (100)	269	3			
467	Weibel	621	11m- 7y	1.9	137	55/58 (95)	71	57/58 (98)	7	58/58 (100)	146	4			
473	McCollum	621										5			
484	Gershon	621	13m-15y		39							6			
511	Villarejos	60664	8m-11y	3.3	50	9/11 (82)	20	10/11 (91)	5	11/11 (100)	226	7			
		60665	11m- 7y	3.3	50	4/5 (80)	25	4/5 (80)	11	5/5 (100)	169				
		60666	11m-11y	4.2	50	2/2 (100)	28	2/2 (100)	8	2/2 (100)	256				
513	Weibel	60664	12m- 7y	1.7	53	28/30 (93)	70	29/30 (97)	19	30/30 (100)	256	8			
		60665	12m- 4y	1.5	54	33/34 (97)	70	33/34 (97)	23	33/34 (97)	200				
		60666	11m- 4y	1.4	56	32/33 (97)	66	32/33 (97)	26	32/33 (97)	251				
		Totals			834	264/279 (95)	63	268/279 (96)	11	277/279 (99)	178				

4/24/78

Table -0

Clinical Complaints Reported Among Children Who Received a 0.5 Ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot No. 621/C-D763 (Study #443)

Clinical Complaint	Total Vaccinees (102 Children)						Initially Seronegative to: Measles, Mumps and Rubella (68 Children)					
	Days Post-Vaccination					No. with Complaint	Days Post-Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Soreness at Injection Site	4 (4.2)			1 (1.0)		5	2 (3.0)					2
Lymphadenopathy	2 (2.1)	3 (3.1)		2 (2.1)	2 (2.1)	6	1 (1.5)	1 (1.5)		2 (3.0)	2 (3.0)	3
Measles-Like Rash	1 (1.0)	9 (9.4)	6 (6.2)	1 (1.0)		11	1 (1.5)	7 (10.4)	5 (7.5)	1 (1.5)		9
Arthralgia			1 (1.0)	1 (1.0)		1			1 (1.5)	1 (1.5)		1
Myalgia		1 (1.0)				1		1 (1.5)				1
Irritability	3 (3.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	4	2 (2.9)	2 (2.9)	1 (1.5)	1 (1.5)		3
Headache	2 (2.1)	2 (2.1)				2	2 (3.0)	2 (3.0)				2
Upper Respiratory Illness	38 (39.6)	37 (38.5)	24 (25.0)	35 (36.5)	32 (33.3)	64	28 (41.8)	27 (40.3)	20 (29.8)	25 (37.3)	20 (29.8)	46
Otitis	1 (1.0)	7 (7.3)	2 (2.1)	5 (5.2)	4 (4.2)	14	1 (1.5)	4 (6.0)	2 (3.0)	3 (4.5)	2 (3.0)	9
Ophthalmopathy	2 (2.1)	3 (3.1)	2 (2.1)	4 (4.2)	2 (2.1)	6	2 (3.0)	3 (4.5)	2 (3.0)	4 (6.0)	2 (3.0)	6
Gastrointestinal Illness	18 (18.7)	24 (25.0)	9 (9.4)	17 (17.7)	15 (15.6)	43	14 (20.9)	19 (28.4)	9 (13.4)	14 (20.9)	11 (16.4)	35
Anorexia	13 (13.5)	19 (19.8)	8 (8.3)	10 (10.4)	13 (13.5)	28	10 (14.9)	12 (17.9)	6 (9.0)	9 (13.4)	11 (16.4)	20
Fatigue				1 (1.0)		1				1 (1.5)		1
Rash-Chafing, Diaper, Heat, Herpes	4 (4.2)	4 (4.2)	1 (1.0)	4 (4.2)	5 (5.2)	12	3 (4.5)	4 (6.0)	1 (1.5)	3 (4.5)	3 (4.5)	9
Allergy, Asthma	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)	3 (3.1)	6		1 (1.5)	2 (3.0)	1 (1.5)		3
Fever	1 (1.0)	1 (1.0)		2 (2.1)	1 (1.0)	4		1 (1.5)		1 (1.5)		2
Sudoresis	1 (1.0)					1	1 (1.5)					1
Teething	3 (3.0)			1 (1.0)	3 (3.0)	6	3 (4.4)			1 (1.5)	3 (4.4)	6
Persons with Complaints:	50 (52.1)	50 (52.1)	33 (34.4)	43 (44.8)	44 (45.8)	78	38 (56.7)	38 (56.7)	29 (43.3)	32 (47.8)	30 (44.8)	58
Persons with No Complaints:	46 (47.9)	46 (47.9)	63 (65.6)	53 (55.2)	52 (54.2)	18	29 (43.3)	29 (43.3)	38 (56.7)	35 (52.2)	37 (55.2)	9
Negative Physician Surveillance	6	6	6	6	6	6	1	1	1	1	1	1

Table 9

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-ER10 (Study #459)

Clinical Complaint	Total Vaccinees (41 Children)					No. with Complaint	Initially Seronegatives (16 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site: Soreness	2 (4.92)					2						0
Systemic: Measles-Like Rash		4 (9.8)	2 (4.9)			5			1 (6.3)			1
Irritability	1 (2.4)	3 (7.3)	2 (4.9)		3 (7.5)	6	1 (6.3)				1 (6.7)	2
Anorexia	8 (19.5)	5 (12.2)	8 (19.5)	9 (22.0)	7 (17.5)	20	3 (18.8)	1 (6.3)	2 (12.5)	3 (18.8)	3 (20.0)	6
Disturbed Sleep		1 (2.4)				1		1 (6.3)				1
Upper Respiratory Illness	16 (39.0)	17 (41.5)	10 (24.4)	11 (26.8)	16 (40.0)	28	5 (31.3)	5 (31.3)	2 (12.5)	6 (37.5)	7 (46.7)	10
Otitis		2 (4.9)	1 (2.4)	3 (7.3)	3 (7.5)	8		1 (6.3)	1 (6.3)	2 (12.5)	1 (6.7)	4
Ophthalmopathy	3 (7.3)	1 (2.4)			3 (7.5)	7		1 (6.3)				1
Gastrointestinal Illness	9 (22.0)	9 (22.0)	6 (14.6)	10 (24.4)	9 (22.5)	24	3 (18.8)	1 (6.3)	2 (12.5)	5 (31.3)	3 (20.0)	10
Nonspecific Rash	2 (4.9)	4 (9.8)	2 (4.9)	3 (7.3)	3 (7.5)	5	1 (6.3)	2 (12.5)	2 (12.5)	2 (12.5)	1 (6.7)	3
Varicella				1 (2.4)		1				1 (6.3)		1
Allergy		1 (2.4)				1		1 (6.3)				1
Teething	1 (2.4)	3 (7.3)	1 (2.4)	1 (2.4)	2 (5.0)	4	1 (6.3)	1 (6.3)	1 (6.3)	1 (6.3)	1 (6.7)	1
Herpes-Type Rash	1 (2.4)					1						0
Persons with Complaint:	20 (48.8)	26 (63.4)	18 (43.9)	16 (39.0)	22 (55.0)	34	7 (43.8)	8 (50.0)	6 (37.5)	8 (50.0)	9 (60.0)	14
Persons with No Complaint:	21 (51.2)	15 (36.6)	23 (56.1)	25 (61.0)	18 (45.0)	7	9 (56.3)	8 (50.0)	10 (62.5)	8 (50.0)	6 (40.0)	2
Negative Surveillance					1						1	

Table 11

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-8763 (Study #467)

Clinical Complaint	Total Vaccinees (117 Children)					No. with Complaint	Initially Seronegatives (61 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-62		0-4	5-12	13-18	19-28	29-62	
Soreness at Injection Site	2 (2.2)	1 (1.1)	1 (1.1)			3	1 (2.1)	1 (2.1)	1 (2.1)			2
Lymphadenopathy		2 (2.2)		1 (1.1)		3		2 (4.3)		1 (2.1)		3
Measles-Like Rash	1 (1.1)	5 (5.6)	3 (3.4)			7	1 (2.1)	4 (8.5)	1 (2.1)			5
Headache		1 (1.1)		1 (1.1)	1 (1.1)	3		1 (2.1)				1
Irritability	4 (4.4)	4 (4.5)		1 (1.1)		8	3 (6.3)	1 (2.1)				4
Fever-Temperature Not Reported	1 (1.1)	1 (1.1)				2		1 (2.1)				1
Anorexia	10 (11.1)	12 (13.5)	6 (6.7)	7 (8.0)	6 (6.8)	23	5 (10.4)	7 (14.9)	4 (8.3)	2 (4.3)	1 (2.1)	11
Flush					1 (1.1)	1						0
Disturbed Sleep	2 (2.2)					2						0
Hyalgia	1 (1.1)					1	1 (2.1)					1
Upper Respiratory Illness	15 (16.7)	29 (32.6)	17 (19.1)	20 (22.7)	31 (35.2)	53	6 (12.5)	13 (27.7)	9 (18.8)	9 (19.1)	10 (21.3)	22
Otitis	1 (1.1)	2 (2.2)	2 (2.2)	1 (1.1)	1 (1.1)	2		1 (2.1)	1 (2.1)			1
Ophthalmopathy		5 (5.6)	4 (4.5)	3 (3.4)	4 (4.5)	9		3 (6.4)	3 (6.3)	2 (4.3)	1 (2.1)	4
Gastrointestinal Illness	9 (10.0)	15 (16.9)	10 (11.2)	12 (13.6)	13 (14.8)	31	4 (8.3)	12 (25.5)	6 (12.5)	7 (14.9)	4 (8.5)	16
Nonspecific Rash	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	4 (4.5)	6		1 (2.1)				1
Poison Ivy		1 (1.1)	1 (1.1)			1						0
Allergy		1 (1.1)		1 (1.1)		2		1 (2.1)		1 (2.1)		2
Teething	1 (1.1)	4 (6.5)	4 (6.5)	2 (2.3)	2 (2.3)	10	1 (2.1)	2 (4.3)	2 (4.2)			5
Negative Surveillance	27	28	28	29	29	27	13	14	13	14	14	13
Persons with Complaint:	30 (33.3)	44 (49.4)	28 (31.5)	30 (34.1)	37 (42.0)	56	12 (25.0)	21 (46.7)	14 (29.2)	14 (29.8)	13 (27.7)	25
Persons with No Complaint:	60 (66.7)	65 (50.6)	61 (68.5)	58 (65.9)	51 (58.0)	33	36 (75.0)	26 (55.3)	34 (70.8)	33 (70.2)	34 (72.3)	23

Table 12

Clinical Complaints Reported Among Children Who Received a 1.0 ml Dose of Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #621/C-D763 (Study #467)

Clinical Complaint	Total Vaccinees (20 Children)					No. with Complaint	Initially Seronegatives (11 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Soreness at Injection Site	1 (5.9%)					1	1 (10.0)					1
Lymphadenopathy	1 (5.9)					1	1 (10.0)					1
Arthralgia			1 (5.9)			1						0
Measles-Like Rash			1 (5.9)			1			1 (10.0)			1
Irritability	1 (5.9)	1 (5.9)				1	1 (10.0)	1 (10.0)				1
Fever - Temperature Not Reported				1 (5.9)		1				1 (10.0)		1
Anorexia			1 (5.9)	1 (5.9)		2			1 (10.0)			1
Upper Respiratory Illness	4 (23.5)	5 (29.4)	2 (11.8)	4 (23.5)	1 (5.9)	8	1 (10.0)	1 (10.0)		2 (20.0)		4
Otitis			1 (5.9)	1 (5.9)	1 (5.9)	1			1 (10.0)	1 (10.0)	1 (10.0)	1
Gastrointestinal Illness	3 (17.6)		1 (5.9)	1 (5.9)		4	2 (20.0)		1 (10.0)			2
Impetigo				1 (5.9)		1				1 (10.0)		1
Negative Surveillance	3	3	3	3	3	3	1	1	1	1	1	1
Persons with Complaint:	7 (41.2)	6 (35.3)	5 (29.4)	5 (29.4)	2 (11.8)	9	3 (30.0)	2 (20.0)	2 (20.0)	3 (30.0)	1 (10.0)	5
Persons with No Complaint:	10 (58.8)	11 (64.7)	12 (70.6)	12 (70.6)	15 (88.2)	8	7 (70.0)	8 (80.0)	8 (80.0)	7 (70.0)	9 (90.0)	5

Table 13

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (MMV-77) Virus Vaccine, M-M-R (Study #467)

Clinical Complaint	Total Vaccinees (138 Children)					No. with Complaint	Initially Seronegatives (70 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Sites:	7 (6.9%)					7	3 (5.7)					3
Soreness	6					6	2					2
Soreness and Induration	1					1	1					1
Systemic:												
Measles-like Rash		5 (5.0)	2 (2.0)			5		1 (1.9)				1
Headache	1 (1.0)		1 (1.0)		2 (2.0)	2					1 (1.9)	1
Irritability	3 (3.0)	4 (4.0)	2 (2.0)	3 (3.0)		9	2 (3.8)	1 (1.9)		1 (1.9)		4
Anorexia	11 (10.9)	17 (16.8)	5 (5.0)	6 (5.9)	4 (4.0)	24	6 (11.3)	9 (17.0)	1 (1.9)	3 (5.7)	3 (5.7)	14
Flush	1 (1.0)					1						0
Disturbed Sleep		1 (1.0)				1						0
Hyalgia	2 (2.0)					2	1 (1.9)					1
Upper Respiratory Illness	18 (17.8)	19 (18.8)	15 (14.9)	18 (17.8)	24 (23.8)	65	10 (18.9)	9 (17.0)	6 (11.3)	7 (13.2)	8 (15.1)	20
Otitis	1 (1.0)	4 (4.0)	2 (2.0)	1 (1.0)	1 (1.0)	7	1 (1.9)	2 (3.8)				3
Ophthalmopathy	2 (2.0)	3 (3.0)		1 (1.0)	2 (2.0)	6	2 (3.8)	2 (3.8)				4
Gastrointestinal Illness	15 (14.9)	12 (11.9)	5 (5.0)	5 (5.0)	6 (5.9)	27	7 (13.2)	3 (5.7)	3 (5.7)	2 (3.8)	4 (7.5)	11
Rash-Non-specific	1 (1.0)	3 (3.0)	5 (5.0)	3 (3.0)	4 (4.0)	12	1 (1.9)	1 (1.9)	4 (7.5)	1 (1.9)	1 (1.9)	6
Varicella				1 (1.0)	1 (1.0)	1						0
Other*	1 (1.0)	1 (1.0)				2	1 (1.9)					1
Genitourinary Infection				1 (1.0)	1 (1.0)	1						0
Allergy	2 (2.0)	2 (2.0)		1 (1.0)		3	2 (3.8)	2 (3.8)				2
Teething		2 (2.0)	4 (4.0)	5 (5.0)	2 (2.0)	8		1 (1.9)		1 (1.9)	2 (3.8)	3
Negative Surveillance	37	37	37	37	37	37	17	17	17	17	17	17
Persons with Complaint:	36 (27.6)	41 (40.6)	24 (23.8)	26 (25.7)	30 (29.7)	57	20 (37.7)	18 (34.0)	9 (17.0)	10 (18.9)	12 (22.6)	27
Persons with No Complaints	65 (64.4)	60 (59.4)	77 (76.2)	75 (74.3)	71 (70.3)	44	33 (62.3)	35 (66.0)	44 (83.0)	43 (81.1)	41 (77.4)	26

* Includes ingested lighter fluid and bloody nose.

Table 10

Clinical Complaints Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (13 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache	1 (2.0%)	1 (2.0)	1 (2.0)	1 (2.0)		4						0
Irritability	5 (10.0)	8 (16.0)	6 (12.0)	5 (10.0)		18	2 (15.4)	3 (23.1)	3 (23.1)	1 (7.7)		7
Malaise	7 (14.0)	9 (18.0)	4 (8.0)	4 (8.0)		17	3 (23.1)	3 (23.1)	3 (23.1)	2 (15.4)		7
Anorexia		1 (2.0)		1 (2.0)		2				1 (7.7)		1
Upper Respiratory Illness	2 (4.0)	6 (12.0)	3 (6.0)	1 (2.0)		9			2 (15.4)			2
Lower Respiratory Illness	1 (2.0)	1 (2.0)				1	1 (7.7)	1 (7.7)				1
Gastrointestinal Illness	1 (2.0)	3 (6.0)	1 (2.0)	4 (8.0)	2 (4.0)	7			1 (7.7)	2 (15.4)	1 (7.7)	3
Persons with Complaint:	7 (14.0)	9 (18.0)	7 (14.0)	8 (16.0)	2 (4.0)	21	3 (23.1)	3 (23.1)	4 (30.8)	2 (15.4)	1 (7.7)	8
Persons with No Complaint:	43 (86.0)	41 (82.0)	43 (86.0)	42 (84.0)	48 (96.0)	29	10 (76.9)	10 (76.9)	9 (69.2)	11 (84.6)	12 (92.3)	5

Table 11

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-2811 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (6 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache	2 (4.0%)	1 (2.0)	4 (8.0)	2 (4.0)		8		1 (16.7)				1
Irritability	2 (4.0)	9 (18.0)	4 (8.0)	5 (10.0)	3 (6.1)	18		1 (16.7)		1 (16.7)		2
Malaise	2 (4.0)	7 (14.0)	2 (4.0)	3 (6.0)		12		1 (16.7)		1 (16.7)		2
Anorexia		1 (2.0)				1						0
Upper Respiratory Illness	2 (4.0)	4 (8.0)				4						0
Lower Respiratory Illness		1 (2.0)	1 (2.0)			1						0
Gastrointestinal Illness	1 (2.0)	3 (6.0)	2 (4.0)	1 (2.0)		5						0
Persons with Complaint:	2 (4.0)	11 (22.0)	7 (14.0)	6 (12.0)	3 (6.1)	20	0	1 (16.7)	1 (16.7)	1 (16.7)	0	3
Persons with No Complaint:	48 (96.0)	39 (78.0)	43 (86.0)	44 (88.0)	46 (93.9)	30	6 (100)	5 (83.3)	5 (83.3)	5 (83.3)	5 (100)	3
Negative Surveillance	0	0	0	0	1	0	0	0	0	0	1	0

Table 12

Clinical Complaints Reported Among Children Who Received Combined Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-E812 (Study #511)

Clinical Complaint	Total Vaccinees (50 Children)					No. with Complaint	Initially Seronegatives (2 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Headache		2 (4.0%)	4 (8.0)			6			1 (50.0)			1
Irritability	1 (2.0)	9 (18.0)	3 (6.0)	1 (2.0)	2 (4.0)	12						0
Malaise	2 (4.0)	6 (12.0)	4 (8.0)		3 (6.0)	13			1 (50.0)			1
Anorexia	1 (2.0)	3 (6.0)	1 (2.0)			5						0
Upper Respiratory Illness	1 (2.0)	2 (4.0)				2						0
Lower Respiratory Illness		1 (2.0)				1						0
Otitis	1 (2.0)					1						0
Gastrointestinal Illness	1 (2.0)	1 (2.0)	1 (2.0)			2						0
Persons with Complaint:	2 (4.0)	11 (22.0)	6 (12.0)	1 (2.0)	3 (6.0)	17	0	0	1 (50.0)	0	0	1
Persons with No Complaint:	48 (96.0)	39 (78.0)	44 (88.0)	49 (98.0)	47 (94.0)	33	2 (100)	2 (100)	1 (50.0)	2 (100)	2 (100)	1

Table 10

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60664/C-E810 (Study #513)

Clinical Complaint	Total Vaccinees (53 Children)					Initially Seronegatives (30 Children)						
	Days Post Vaccination					No. with Complaint	Days Post Vaccination					No. with Complaint
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (3.9%)					2	1 (3.3)					1
Soreness	2					2	1					1
Systemic:												
Arthralgia	1 (2.0)	1 (2.0)				1						0
Measles-Like Rash		6 (11.8)	1 (2.0)	1 (2.0)		6	4 (13.3)	1 (3.3)	1 (3.3)			4
Headache		1 (2.0)				1						0
Irritability	4 (7.8)	2 (3.9)	1 (2.0)	2 (3.9)	2 (3.9)	8	4 (13.3)	2 (6.7)	1 (3.3)	2 (6.7)	1 (3.3)	7
Anorexia	4 (7.8)	3 (5.9)	1 (2.0)	2 (3.9)	5 (9.8)	10	2 (6.7)	2 (6.7)		2 (6.7)	3 (10.0)	7
Disturbed Sleep			1 (2.0)		1 (2.0)	1						0
Fatigue		1 (2.0)			1 (2.0)	1		1 (3.3)			1 (3.3)	1
Myalgia	1 (2.0)	1 (2.0)				1						0
Upper Respiratory Illness	9 (17.6)	12 (23.5)	7 (13.7)	12 (23.5)	11 (21.6)	25	4 (13.3)	7 (23.3)	6 (20.0)	7 (23.3)	8 (26.7)	14
Otitis				1 (2.0)		1				1 (3.3)		1
Ophthalmopathy	1 (2.0)	1 (2.0)		1 (2.0)	1 (2.0)	2		1 (3.3)		1 (3.3)	1 (3.3)	1
Gastrointestinal Illness	12 (23.5)	11 (21.6)	2 (3.9)	4 (7.8)	5 (9.8)	18	9 (30.0)	9 (30.0)	1 (3.3)	3 (10.0)	4 (13.3)	15
Nonspecific Rash	5 (9.8)	4 (7.8)	4 (7.8)	6 (11.8)	8 (15.7)	15	2 (6.7)	4 (13.3)	4 (13.3)	5 (16.7)	5 (16.7)	10
Sores on Face		1 (2.0)				1		1 (3.3)				1
Allergy	1 (2.0)		1 (2.0)			2	1 (3.3)		1 (3.3)			2
Teething	2 (3.9)	4 (7.8)	1 (2.0)	2 (3.9)	3 (5.9)	9	1 (3.3)	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	7
Herpes-Type Rash		1 (2.0)		1 (2.0)		2		1 (3.3)		1 (3.3)		2
Persons with Complaint:	24 (47.1)	27 (52.9)	12 (23.5)	18 (35.3)	19 (37.3)	39	14 (46.7)	19 (63.3)	9 (30.0)	12 (40.0)	13 (43.3)	25
Persons with No Complaint:	27 (52.9)	24 (47.1)	39 (76.5)	33 (64.7)	32 (62.7)	12	16 (53.3)	11 (36.7)	21 (70.0)	18 (60.0)	17 (56.7)	5
Negative Surveillance	2	2	2	2	2	2	0	0	0	0	0	0

Table 11

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60665/C-E811 (Study #513)

Clinical Complaint	Total Vaccinees (54 Children)					No. with Complaint	Initially Seronegatives (34 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	2 (3.8)					2	2 (5.9)					2
Soreness	1					1	1					1
Erythema and Soreness	1					1	1					1
Systemic:												
Lymphadenopathy	2 (3.8)	1 (1.9)				3	1 (2.9)	1 (2.9)				2
Measles-Like Rash		5 (9.6)	4 (7.7)	1 (1.9)		7		3 (8.8)	2 (5.9)			4
Irritability	4 (7.7)	6 (11.5)	1 (1.9)	1 (1.9)	2 (3.8)	9	4 (11.8)	4 (11.8)		1 (2.9)	2 (5.9)	7
Malaise	1 (1.9)	1 (1.9)				1	1 (2.9)	1 (2.9)				1
Anorexia	5 (9.6)	5 (9.6)	3 (5.8)	2 (3.8)	4 (7.7)	13	3 (8.8)	4 (11.8)	2 (5.9)	1 (2.9)	3 (8.8)	9
Disturbed Sleep	1 (1.9)	1 (1.9)	1 (1.9)			2	1 (2.9)	1 (2.9)				1
Fatigue	2 (3.8)					2	2 (5.9)					2
Upper Respiratory Illness	10 (19.2)	9 (17.3)	5 (9.6)	10 (19.2)	11 (21.2)	25	4 (11.8)	6 (17.6)	4 (11.8)	6 (17.6)	7 (20.6)	15
Ortitis	2 (3.8)	2 (3.8)	2 (3.8)	1 (1.9)	1 (1.9)	4	2 (5.9)	1 (2.9)	1 (2.9)	1 (2.9)	1 (2.9)	2
Ophthalmopathy	1 (1.9)	3 (5.8)		1 (1.9)	1 (1.9)	5	1 (2.9)	2 (5.9)		1 (2.9)	1 (2.9)	4
Gastrointestinal Illness	9 (17.3)	10 (19.2)	5 (9.6)	4 (7.7)	6 (11.5)	18	6 (17.6)	7 (20.6)	3 (8.8)	3 (8.8)	5 (14.7)	11
Nonspecific Rash	4 (7.7)	3 (5.8)		2 (3.8)	2 (3.8)	7	3 (8.8)	3 (8.8)		2 (5.9)	2 (5.9)	6
Allergy	1 (1.9)					1	1 (2.9)					1
Teething	1 (1.9)	1 (1.9)	1 (1.9)	3 (5.8)	3 (5.8)	4	1 (2.9)	1 (2.9)		1 (2.9)	1 (2.9)	2
Persons with Complaint:	24 (46.2)	26 (50.0)	18 (34.6)	21 (40.4)	18 (34.6)	36	16 (47.1)	18 (52.9)	11 (32.4)	13 (38.2)	12 (35.3)	23
Persons with No Complaint:	28 (53.8)	26 (50.0)	34 (65.4)	31 (59.6)	34 (65.4)	16	18 (52.9)	16 (47.1)	23 (67.6)	21 (61.8)	22 (64.7)	11
Negative Surveillance:	2	2	2	2	2	2	0	0	0	0	0	0

Table 12

Clinical Complaints Reported Among Children Who Received Combined
Live Measles-Mumps-Rubella (RA 27/3) Virus Vaccine, Lot #60666/C-R812 (Study #513)

Clinical Complaint	Total Vaccinees (56 Children)					No. with Complaint	Initially Seronegatives (33 Children)					No. with Complaint
	Days Post Vaccination						Days Post Vaccination					
	0-4	5-12	13-18	19-28	29-42		0-4	5-12	13-18	19-28	29-42	
Injection Site:	4 (7.4%)					4	3 (9.1)					3
Soreness	4					4	3					3
Systemic:												
Lymphadenopathy				1 (1.9)		1			1 (3.0)			1
Measles-Like Rash		6 (11.1)	2 (3.7)	1 (1.9)		8		4 (12.1)	2 (6.1)	1 (3.0)		6
Headache	1 (1.9)					1						0
Irritability	4 (7.4)	4 (7.4)	3 (5.6)	3 (5.6)	2 (3.7)	8	2 (6.1)	3 (9.1)	2 (6.1)	3 (9.1)	2 (6.1)	5
Anorexia	6 (11.1)	9 (16.7)	1 (1.9)	2 (3.7)	11 (20.4)	20	4 (12.1)	5 (15.2)			9 (27.3)	13
Disturbed Sleep	1 (1.9)	2 (3.7)				2	1 (3.0)	2 (6.1)				2
Fatigue		1 (1.9)		1 (1.9)		1		1 (3.0)		1 (3.0)		1
Myalgia				1 (1.9)	2 (3.7)	2				1 (3.0)	1 (3.0)	1
Upper Respiratory Illness	13 (24.1)	19 (35.2)	13 (24.1)	14 (25.9)	15 (27.8)	30	10 (30.3)	12 (36.4)	9 (27.3)	11 (33.3)	12 (36.4)	20
Otitis	1 (1.9)	2 (3.7)		2 (3.7)	2 (3.7)	5		1 (3.0)		2 (6.1)	2 (6.1)	3
Ophthalmopathy	2 (3.7)	1 (1.9)		1 (1.9)	1 (1.9)	4	1 (3.0)			1 (3.0)	1 (3.0)	2
Gastrointestinal Illness	6 (11.1)	4 (7.4)	4 (7.4)	5 (9.3)	7 (13.0)	18	4 (12.1)		3 (9.1)	4 (12.1)	3 (9.1)	12
Nonspecific Rash	4 (7.4)	8 (14.8)	6 (11.1)	7 (13.0)	6 (11.1)	19	3 (9.1)	5 (15.2)	4 (12.1)	4 (12.1)	4 (12.1)	13
Sore from Venipuncture	1 (1.9)					1	1 (3.0)					1
Teething		3 (5.6)	2 (3.7)	3 (5.6)	3 (5.6)	5		3 (9.1)	2 (6.1)	3 (9.1)	2 (6.1)	4
Herpes-Type Rash		1 (1.9)				1		1 (3.0)				1
Persons with Complaint:	27 (50.0)	33 (61.1)	22 (40.7)	24 (44.4)	25 (46.3)	41	20 (60.6)	22 (66.7)	16 (48.5)	19 (57.6)	17 (51.5)	27
Persons with No Complaint:	27 (50.0)	21 (38.9)	32 (59.3)	30 (55.6)	29 (53.7)	13	13 (39.4)	11 (33.3)	17 (51.5)	14 (42.4)	16 (48.5)	6
Negative Surveillance	2	2	2	2	2	2	0	0	0	0	0	0

Exhibit CC

**NEW YORK CITY OFFICE OF
ADMINISTRATIVE TRIALS AND HEARINGS**

New York City Department of Health and Mental
Hygiene,

Summons No. 30304-19L0

Petitioner,

DECLARATION OF

-against-

JUDITH FRIED

Judith Fried

Child's Date of Birth

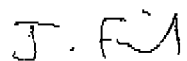
Respondent.

I, Judith Fried, under penalty of perjury, aver the following:

1. I was issued Summons Number 30304- 19L0 from the New York Department of Health and Mental Hygiene.
2. The Summons references my child, H.F.
3. The birthdate of the child is August 2, 2018.
4. The DATE AND TIME OF OCCURRENCE list on the Summons is May 10, 2019 at 2:22 PM.
5. On the date of occurrence, the child was less than twelve months old.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Date: August 23, 2019



Judith Fried

Exhibit D

M-M-R® II **(MEASLES, MUMPS, and** **RUBELLA VIRUS VACCINE LIVE)**

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) is a live virus vaccine for vaccination against measles (rubeola), mumps, and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) MUMPSVAX® (Mumps Virus Vaccine Live), the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) MERUVAX® II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts.{1,2}

The growth medium for measles and mumps is Medium 199 (a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum) containing SPGA (sucrose, phosphate, glutamate, and recombinant human albumin) as stabilizer and neomycin.

The growth medium for rubella is Minimum Essential Medium (MEM) [a buffered salt solution containing vitamins and amino acids and supplemented with fetal bovine serum] containing recombinant human albumin and neomycin. Sorbitol and hydrolyzed gelatin stabilizer are added to the individual virus harvests.

The cells, virus pools, and fetal bovine serum are all screened for the absence of adventitious agents.

The reconstituted vaccine is for subcutaneous administration. Each 0.5 mL dose contains not less than 1,000 TCID₅₀ (tissue culture infectious doses) of measles virus; 12,500 TCID₅₀ of mumps virus; and 1,000 TCID₅₀ of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug. M-M-R II, when reconstituted as directed, is clear yellow.

CLINICAL PHARMACOLOGY

Measles, mumps, and rubella are three common childhood diseases, caused by measles virus, mumps virus (paramyxoviruses), and rubella virus (togavirus), respectively, that may be associated with serious complications and/or death. For example, pneumonia and encephalitis are caused by measles. Mumps is associated with aseptic meningitis, deafness and orchitis; and rubella during pregnancy may cause congenital rubella syndrome in the infants of infected mothers.

The impact of measles, mumps, and rubella vaccination on the natural history of each disease in the United States can be quantified by comparing the maximum number of measles, mumps, and rubella cases reported in a given year prior to vaccine use to the number of cases of each disease reported in 1995. For measles, 894,134 cases reported in 1941 compared to 288 cases reported in 1995 resulted in a 99.97% decrease in reported cases; for mumps, 152,209 cases reported in 1968 compared to 840 cases reported in 1995 resulted in a 99.45% decrease in reported cases; and for rubella, 57,686 cases reported in 1969 compared to 200 cases reported in 1995 resulted in a 99.65% decrease.{3}

Clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons. However, a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose (see also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*).

A study{4} of 6-month-old and 15-month-old infants born to vaccine-immunized mothers demonstrated that, following vaccination with ATTENUVAX, 74% of the 6-month-old infants developed detectable neutralizing antibody (NT) titers while 100% of the 15-month-old infants developed NT. This rate of seroconversion is higher than that previously reported for 6-month-old infants born to naturally immune mothers tested by HI assay. When the 6-month-old infants of immunized mothers were revaccinated at 15

months, they developed antibody titers equivalent to the 15-month-old vaccinees. The lower seroconversion rate in 6-month-olds has two possible explanations: 1) Due to the limit of the detection level of the assays (NT and enzyme immunoassay [EIA]), the presence of trace amounts of undetectable maternal antibody might interfere with the seroconversion of infants; or 2) The immune system of 6-month-olds is not always capable of mounting a response to measles vaccine as measured by the two antibody assays.

There is some evidence to suggest that infants who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization.{5,6}

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components.{7-12} These studies also established that seroconversion in response to vaccination against measles, mumps, and rubella paralleled protection from these diseases.{13-15}

Following vaccination, antibodies associated with protection can be measured by neutralization assays, HI, or ELISA (enzyme linked immunosorbent assay) tests. Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in most individuals 11 to 13 years after primary vaccination.{16-18} See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing.

The RA 27/3 rubella strain in M-M-R II elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine{19-25} and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.{26,27} The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.{27-29} The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,{27,29-31} and provide greater confidence for lasting immunity.

INDICATIONS AND USAGE

Recommended Vaccination Schedule

M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

Individuals first vaccinated at 12 months of age or older should be revaccinated prior to elementary school entry. Revaccination is intended to seroconvert those who do not respond to the first dose. The Advisory Committee on Immunization Practices (ACIP) recommends administration of the first dose of M-M-R II at 12 to 15 months of age and administration of the second dose of M-M-R II at 4 to 6 years of age.{32} In addition, some public health jurisdictions mandate the age for revaccination. Consult the complete text of applicable guidelines regarding routine revaccination including that of high-risk adult populations.

Measles Outbreak Schedule

Infants Between 6 to 12 Months of Age

Local health authorities may recommend measles vaccination of infants between 6 to 12 months of age in outbreak situations. This population may fail to respond to the components of the vaccine. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established. The younger the infant, the lower the likelihood of seroconversion (see CLINICAL PHARMACOLOGY). Such infants should receive a second dose of M-M-R II between 12 to 15 months of age followed by revaccination at elementary school entry.{32}

Unnecessary doses of a vaccine are best avoided by ensuring that written documentation of vaccination is preserved and a copy given to each vaccinee's parent or guardian.

Other Vaccination Considerations

Non-Pregnant Adolescent and Adult Females

Immunization of susceptible non-pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see below and PRECAUTIONS). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury.{33}

Women of childbearing age should be advised not to become pregnant for 3 months after vaccination and should be informed of the reasons for this precaution.

The ACIP has stated "If it is practical and if reliable laboratory services are available, women of childbearing age who are potential candidates for vaccination can have serologic tests to determine susceptibility to rubella. However, with the exception of premarital and prenatal screening, routinely performing serologic tests for all women of childbearing age to determine susceptibility (so that vaccine is given only to proven susceptible women) can be effective but is expensive. Also, 2 visits to the health-care provider would be necessary — one for screening and one for vaccination. Accordingly, rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing — and may be preferable, particularly when costs of serology are high and follow-up of identified susceptible women for vaccination is not assured."{33}

Postpubertal females should be informed of the frequent occurrence of generally self-limited arthralgia and/or arthritis beginning 2 to 4 weeks after vaccination (see ADVERSE REACTIONS).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (see PRECAUTIONS, *Nursing Mothers*).

Other Populations

Previously unvaccinated children older than 12 months who are in contact with susceptible pregnant women should receive live attenuated rubella vaccine (such as that contained in monovalent rubella vaccine or in M-M-R II) to reduce the risk of exposure of the pregnant woman.

Individuals planning travel outside the United States, if not immune, can acquire measles, mumps, or rubella and import these diseases into the United States. Therefore, prior to international travel, individuals known to be susceptible to one or more of these diseases can either receive the indicated monovalent vaccine (measles, mumps, or rubella), or a combination vaccine as appropriate. However, M-M-R II is preferred for persons likely to be susceptible to mumps and rubella; and if monovalent measles vaccine is not readily available, travelers should receive M-M-R II regardless of their immune status to mumps or rubella.{34-36}

Vaccination is recommended for susceptible individuals in high-risk groups such as college students, health-care workers, and military personnel.{33,34,37}

According to ACIP recommendations, most persons born in 1956 or earlier are likely to have been infected with measles naturally and generally need not be considered susceptible. All children, adolescents, and adults born after 1956 are considered susceptible and should be vaccinated, if there are no contraindications. This includes persons who may be immune to measles but who lack adequate documentation of immunity such as: (1) physician-diagnosed measles, (2) laboratory evidence of measles immunity, or (3) adequate immunization with live measles vaccine on or after the first birthday.{34}

The ACIP recommends that "Persons vaccinated with inactivated vaccine followed within 3 months by live vaccine should be revaccinated with two doses of live vaccine. Revaccination is particularly important when the risk of exposure to wild-type measles virus is increased, as may occur during international travel."{34}

Post-Exposure Vaccination

Vaccination of individuals exposed to wild-type measles may provide some protection if the vaccine can be administered within 72 hours of exposure. If, however, vaccine is given a few days before exposure, substantial protection may be afforded.{34,38,39} There is no conclusive evidence that vaccination of individuals recently exposed to wild-type mumps or wild-type rubella will provide protection.{33,37}

Use With Other Vaccines

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including gelatin.{40}

Do not give M-M-R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and PRECAUTIONS, *Pregnancy*).

Anaphylactic or anaphylactoid reactions to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).

Febrile respiratory illness or other active febrile infection. However, the ACIP has recommended that all vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper respiratory infection with or without low-grade fever, or other low-grade febrile illness.{41}

Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.

Primary and acquired immunodeficiency states, including patients who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency viruses;{41-43} cellular immune deficiencies; and hypogammaglobulinemic and dysgammaglobulinemic states. Measles inclusion body encephalitis{44} (MIBE), pneumonitis{45} and death as a direct consequence of disseminated measles vaccine virus infection have been reported in immunocompromised individuals inadvertently vaccinated with measles-containing vaccine.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

WARNINGS

Due caution should be employed in administration of M-M-R II to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination (see ADVERSE REACTIONS).

Hypersensitivity to Eggs

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution, having adequate treatment on hand should a reaction occur (see PRECAUTIONS).{46}

However, the AAP has stated, "Most children with a history of anaphylactic reactions to eggs have no untoward reactions to measles or MMR vaccine. Persons are not at increased risk if they have egg allergies that are not anaphylactic, and they should be vaccinated in the usual manner. In addition, skin testing of egg-allergic children with vaccine has not been predictive of which children will have an immediate hypersensitivity reaction...Persons with allergies to chickens or chicken feathers are not at increased risk of reaction to the vaccine."{47}

Hypersensitivity to Neomycin

The AAP states, "Persons who have experienced anaphylactic reactions to topically or systemically administered neomycin should not receive measles vaccine. Most often, however, neomycin allergy manifests as a contact dermatitis, which is a delayed-type (cell-mediated) immune response rather than anaphylaxis. In such persons, an adverse reaction to neomycin in the vaccine would be an erythematous, pruritic nodule or papule, 48 to 96 hours after vaccination. A history of contact dermatitis to neomycin is not a contraindication to receiving measles vaccine."{47}

Thrombocytopenia

Individuals with current thrombocytopenia may develop more severe thrombocytopenia following vaccination. In addition, individuals who experienced thrombocytopenia with the first dose of M-M-R II (or its component vaccines) may develop thrombocytopenia with repeat doses. Serologic status may be evaluated to determine whether or not additional doses of vaccine are needed. The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases (see ADVERSE REACTIONS).

PRECAUTIONS

General

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

Special care should be taken to ensure that the injection does not enter a blood vessel.

Children and young adults who are known to be infected with human immunodeficiency viruses and are not immunosuppressed may be vaccinated. However, vaccinees who are infected with HIV should be monitored closely for vaccine-preventable diseases because immunization may be less effective than for uninfected persons (see CONTRAINDICATIONS).{42,43}

Vaccination should be deferred for 3 months or longer following blood or plasma transfusions, or administration of immune globulin (human).{47}

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7 to 28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk.{33} However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see *Nursing Mothers*).

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either before or simultaneously with M-M-R II.

Children under treatment for tuberculosis have not experienced exacerbation of the disease when immunized with live measles virus vaccine;{48} no studies have been reported to date of the effect of measles virus vaccines on untreated tuberculous children. However, individuals with active untreated tuberculosis should not be vaccinated.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

The health-care provider should determine the current health status and previous vaccination history of the vaccinee.

The health-care provider should question the patient, parent, or guardian about reactions to a previous dose of M-M-R II or other measles-, mumps-, or rubella-containing vaccines.

Information for Patients

The health-care provider should provide the vaccine information required to be given with each vaccination to the patient, parent, or guardian.

The health-care provider should inform the patient, parent, or guardian of the benefits and risks associated with vaccination. For risks associated with vaccination see WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Patients, parents, or guardians should be instructed to report any serious adverse reactions to their health-care provider who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.{49}

Pregnancy should be avoided for 3 months following vaccination, and patients should be informed of the reasons for this precaution (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, CONTRAINDICATIONS, and PRECAUTIONS, *Pregnancy*).

Laboratory Tests

See INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females*, for Rubella Susceptibility Testing, and CLINICAL PHARMACOLOGY.

Drug Interactions

See DOSAGE AND ADMINISTRATION, *Use With Other Vaccines*.

Immunosuppressive Therapy

The immune status of patients about to undergo immunosuppressive therapy should be evaluated so that the physician can consider whether vaccination prior to the initiation of treatment is indicated (see CONTRAINDICATIONS and PRECAUTIONS).

The ACIP has stated that "patients with leukemia in remission who have not received chemotherapy for at least 3 months may receive live virus vaccines. Short-term (<2 weeks), low- to moderate-dose systemic corticosteroid therapy, topical steroid therapy (e.g. nasal, skin), long-term alternate-day treatment with low to moderate doses of short-acting systemic steroid, and intra-articular, bursal, or tendon injection of corticosteroids are not immunosuppressive in their usual doses and do not contraindicate the administration of [measles, mumps, or rubella vaccine]."{33,34,37}

Immune Globulin

Administration of immune globulins concurrently with M-M-R II may interfere with the expected immune response.{33,34,47}

See also PRECAUTIONS, *General*.

Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination (see INDICATIONS AND USAGE, *Non-Pregnant Adolescent and Adult Females* and CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: (1) In a 10-year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome;{50} (2) Mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion. Although mumps vaccine virus has been shown to infect the placenta and fetus, there is no evidence that it causes congenital malformations in humans;{37} and (3) Reports have indicated that contracting wild-type measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to infection with wild-type measles during pregnancy.{51,52} There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse fetal effects.

Nursing Mothers

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunized with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants.{53} In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.{54,55} Caution should be exercised when M-M-R II is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established (see also CLINICAL PHARMACOLOGY). Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

Geriatric Use

Clinical studies of M-M-R II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of monovalent or bivalent vaccine containing measles, mumps, or rubella:

Body as a Whole

Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and bronchial spasm in individuals with or without an allergic history.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Arthralgia and/or arthritis (usually transient and rarely chronic), and polyneuritis are features of infection with wild-type rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children. This type of involvement as well as myalgia and paresthesia, have also been reported following administration of MERUVAX II.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. Only rarely have vaccine recipients developed chronic joint symptoms.

Following vaccination in children, reactions in joints are uncommon and generally of brief duration. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-26%),{17,56,57} and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in women older than 35 years, these reactions are generally well tolerated and rarely interfere with normal activities.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS); subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; paresthesia.

Encephalitis and encephalopathy have been reported approximately once for every 3 million doses of M-M-R II or measles-, mumps-, and rubella-containing vaccine administered since licensure of these vaccines.

The risk of serious neurological disorders following live measles virus vaccine administration remains less than the risk of encephalitis and encephalopathy following infection with wild-type measles (1 per 1000 reported cases).{58,59}

In severely immunocompromised individuals who have been inadvertently vaccinated with measles-containing vaccine; measles inclusion body encephalitis, pneumonitis, and fatal outcome as a direct consequence of disseminated measles vaccine virus infection have been reported (see CONTRAINDICATIONS). In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of infection with wild-type measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with infection with wild-type measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Centers for Disease Control and Prevention suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.{60}

Cases of aseptic meningitis have been reported to VAERS following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Respiratory System

Pneumonia; pneumonitis (see CONTRAINDICATIONS); sore throat; cough; rhinitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; urticaria; rash; measles-like rash; pruritis.

Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); swelling; induration; tenderness; vesiculation at injection site; Henoch-Schönlein purpura; acute hemorrhagic edema of infancy.

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.

Urogenital System

Epididymitis; orchitis.

Other

Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see CONTRAINDICATIONS). No deaths or permanent sequelae were reported in a published post-marketing surveillance study in Finland involving 1.5 million children and adults who were vaccinated with M-M-R II during 1982 to 1993.{61}

Under the National Childhood Vaccine Injury Act of 1986, health-care providers and manufacturers are required to record and report certain suspected adverse events occurring within specific time periods after vaccination. However, the U.S. Department of Health and Human Services (DHHS) has established a Vaccine Adverse Event Reporting System (VAERS) which will accept all reports of suspected events.{49} A VAERS report form as well as information regarding reporting requirements can be obtained by calling VAERS 1-800-822-7967.

DOSAGE AND ADMINISTRATION*FOR SUBCUTANEOUS ADMINISTRATION*

Do not inject intravascularly.

The dose for any age is 0.5 mL administered subcutaneously, preferably into the outer aspect of the upper arm.

The recommended age for primary vaccination is 12 to 15 months.

Revaccination with M-M-R II is recommended prior to elementary school entry. See also INDICATIONS AND USAGE, *Recommended Vaccination Schedule*.

Children first vaccinated when younger than 12 months of age should receive another dose between 12 to 15 months of age followed by revaccination prior to elementary school entry.{32} See also INDICATIONS AND USAGE, *Measles Outbreak Schedule*.

Immune Globulin (IG) is not to be given concurrently with M-M-R II (see PRECAUTIONS, *General* and PRECAUTIONS, *Drug Interactions*).

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Single Dose Vial— First withdraw the entire volume of diluent into the syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. If the lyophilized vaccine cannot be dissolved, discard. Withdraw the entire contents into a syringe and inject the total volume of restored vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. M-M-R II, when reconstituted, is clear yellow.

Use With Other Vaccines

M-M-R II should be given one month before or after administration of other live viral vaccines.

M-M-R II has been administered concurrently with VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)], and PedvaxHIB® [*Haemophilus b* Conjugate Vaccine (Meningococcal Protein Conjugate)] using separate injection sites and syringes. No impairment of immune response to individually tested vaccine antigens was demonstrated. The type, frequency, and severity of adverse experiences observed with M-M-R II were similar to those seen when each vaccine was given alone.

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concurrently with measles, mumps and rubella vaccines is not recommended because there are limited data relating to the simultaneous administration of these antigens.

However, other schedules have been used. The ACIP has stated "Although data are limited concerning the simultaneous administration of the entire recommended vaccine series (i.e., DTaP [or DTwP], IPV [or OPV], Hib with or without Hepatitis B vaccine, and varicella vaccine), data from numerous studies have indicated no interference between routinely recommended childhood vaccines (either live, attenuated, or killed). These findings support the simultaneous use of all vaccines as recommended."{62}

HOW SUPPLIED

No. 4681 — M-M-R II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), **NDC 0006-4681-00**; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Storage

To maintain potency, M-M-R II must be stored between -58°F and +46°F (-50°C to +8°C). Use of dry ice may subject M-M-R II to temperatures colder than -58°F (-50°C).

Protect the vaccine from light at all times, since such exposure may inactivate the viruses.

Before reconstitution, store the lyophilized vaccine at 36°F to 46°F (2°C to 8°C). The diluent may be stored in the refrigerator with the lyophilized vaccine or separately at room temperature. **Do not freeze the diluent.**

It is recommended that the vaccine be used as soon as possible after reconstitution. Store reconstituted vaccine in the vaccine vial in a dark place at 36°F to 46°F (2°C to 8°C) and discard if not used within 8 hours.


For information regarding stability under conditions other than those recommended, call 1-800-MERCK-90.

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Exhibit E

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Adverse Effects of Pertussis and Rubella Vaccines

**A Report of the Committee to Review the Adverse
Consequences of Pertussis and Rubella Vaccines**

Christopher P. Howson, Cynthia J. Howe, and Harvey V.
Fineberg, Editors

Division of Health Promotion and Disease Prevention
INSTITUTE OF MEDICINE

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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this the Institute acts under the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Samuel O. Thier is President of the Institute of Medicine.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliches Museum in Berlin.

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EXECUTIVE SUMMARY

TABLE I-1 Categories of Evidence Reviewed for Each Adverse Event: Is the Evidence Supportive of Causation?^a

Vaccine and Adverse Event (Chapter of Report)	Human Experiments			Animal Experiments			Case-Comparison, Cohort, and Other Controlled Studies			Case Reports and Case Series			Biologic Plausibility		
	Yes ^b	? ^c	No ^d	Yes	?	No	Yes	?	No	Yes	?	No	Yes	?	No
DPT															
Infantile spasms (4)									X			X			
Hypsarhythmia (4)			X												X
Aseptic meningitis (4)							X					X			
Acute encephalopathy ^e (4)				X			X				X				X
Chronic neurologic damage (4)				X			X				X				X
Sudden infant death syndrome (5)									X		X				
Anaphylaxis (6)				X			X			X					X
Autism (6)															
Erythema multiforme or other rash (6)											X				X
Guillain-Barré syndrome (polyneuropathy) (6)												X			
Peripheral mononeuropathy (6)												X			
Hemolytic anemia (6)												X			X
Juvenile diabetes (6)				X			X				X				
Learning disabilities and hyperactivity (6)									X		X				
Protracted inconsolable crying and screaming (6)							X				X				X
Reye syndrome (6)									X				X		

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Vaccine and Adverse Event	Human Experiments			Animal Experiments			Case-Comparison Cohort, and Other Controlled Studies			Case Reports and Case Series			Biologic Plausibility			
	Yes ^b	? ^c	No ^d	Yes	? ^e	No	Yes	? ^e	No	Yes	? ^e	No	Yes	? ^e	No	
(Chapter of Report)																
Shock and "unusual shock-like state" (6)								X								X
Thrombocytopenia (6)												X				
RA, 27/3 Rubella Arthritis (7)	X															
Acute										X						X
Chronic							X			X						X
Radiculoneuritis and other neuropathies (7)												X				X
Thrombocytopenic purpura (7)												X				X

^a Blanks for any given category of evidence indicate that evidence of this kind is lacking.

^b Yes, Evidence of this kind is supportive of causation.

^c ?, Evidence of this kind cannot be classified either as supportive or as not supportive of causation.

^d No, Evidence of this kind is not supportive of causation.

^e Defined in controlled studies reviewed as encephalopathy, encephalitis, or encephalomyelitis.

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EXECUTIVE SUMMARY

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TABLE 1-2 Summary of Conclusions by Adverse Event for DPT^a
 and RA 27/3 MMR^b Vaccines

Conclusion	Adverse Events Reviewed	
	DPT Vaccine	RA 27/3 Rubella Vaccine
1. No evidence bearing on a causal relation ^c	Autism	
2. Evidence insufficient to indicate a causal relation ^d	Aseptic meningitis Chronic neurologic damage Erythema multiforme or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia	Radiculoneuritis and other neuropathies Thrombocytopenic purpura
3. Evidence does not indicate a causal relation ^e	Infantile spasms Hypsarrhythmia Reye syndrome Sudden infant death syndrome	
4. Evidence is consistent with a causal relation ^f	Acute encephalopathy ^g Shock and "unusual shock-like state"	Chronic arthritis
5. Evidence indicates a causal relation ^h	Anaphylaxis Prolonged, inconsolable crying	Acute arthritis

^aEvidence does not differentiate between DPT vaccine and the pertussis component of DPT vaccine except in the case of protracted, inconsolable crying where the evidence implicates the pertussis component specifically.

^bRA 27/3 MMR, Trivalent measles-mumps-rubella vaccine containing the RA 27/3 rubella strain.

^cNo category of evidence was found bearing on a judgment about causation (all categories of evidence left blank in Table 1-1).

^dRelevant evidence in one or more categories was identified but was judged to be insufficient to indicate whether or not a causal relation exists (no category of evidence checked as supporting causation in Table 1-1; exceptions are this designation under biologic plausibility for erythema multiforme and hemolytic anemia).

^eThe available evidence, on balance, does not indicate a causal relation (one or more categories of evidence checked as not supporting causation in Table 1-1, with evidence supporting causation being either absent or outweighed by the other evidence).

^fThe available evidence, on balance, tends to support a causal relation (one or more categories of evidence checked as supporting causation in Table 1-1, with evidence checked as insufficient or not supporting causation being absent or outweighed by the other evidence).

^gDefined in controlled studies reviewed as encephalopathy, encephalitis, or encephalomyelitis.

^hThe available evidence, on balance, supports a causal relation, and the evidence is more persuasive than that for conclusion 4 above (the categories of evidence are coded similarly to those in conclusion 4, with evidence checked as insufficient or not supporting causation in Table 1-1 being absent or less than for 4).

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EXECUTIVE SUMMARY

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- athy, or thrombocytopenia, and between the currently used rubella vaccine (RA 27/3) and radiculoneuritis and other neuropathies or thrombocytopenic purpura;
- that the evidence does not indicate a causal relation between DPT vaccine and infantile spasms, hypsarrhythmia, Reye syndrome, or SIDS;
- that the evidence is consistent with a causal relation between DPT vaccine and acute encephalopathy and shock and "unusual shock-like state," and between RA 27/3 rubella vaccine and chronic arthritis; and
- that the evidence indicates a causal relation between DPT vaccine and anaphylaxis, between the pertussis component of DPT vaccine and protracted, inconsolable crying, and between RA 27/3 rubella vaccine and acute arthritis.¹

RESEARCH NEEDS

In the course of its review, the committee encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent information from case reports and case series, inadequate size or length of follow-up of many population-based epidemiologic studies, and limited capacity of existing surveillance systems of vaccine injury to provide persuasive evidence of causation. The committee found few experimental studies published in relation to the number of epidemiologic studies published. Clearly, if research capacity and accomplishment in these areas are not improved, future reviews of vaccine safety will be similarly handicapped.

With respect to pertussis and rubella vaccines, careful review is needed to identify what sorts of questions might be best answered by further investigations and which kinds of studies could be carried out economically. The availability and introduction of new forms of pertussis vaccine, for example, could offer valuable opportunities for comparison of vaccine safety as well as efficacy. The committee's experience points to fresh possibilities and to the need for such a review.

¹ The available evidence is consistent with a causal relation, but, on balance, is more persuasive than that in the previous bullet.

Exhibit FF

Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Casualty
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Adverse Events Associated with CHILDHOOD VACCINES

Evidence Bearing on Causality

Kathleen R. Stratton, Cynthia J. Howe, and Richard B. Johnston,
Jr., Editors

Vaccine Safety Committee
Division of Health Promotion and Disease Prevention
INSTITUTE OF MEDICINE

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance. This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this the Institute acts under the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Kenneth I. Shine is President of the Institute of Medicine.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatlichemuseum in Berlin.

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EXECUTIVE SUMMARY

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Vaccine and Adverse Event	Biologic Plausibility ^b	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Arthritis	Theoretical only	Indeterminate	No data
Erythema multiforme	Theoretical only	Indeterminate (DT, Td) NO data (T)	No data
Anaphylaxis	Demonstrated	For (T) Indeterminate (DT, Td)	No data
Death from SIDS (DT only) ^e	Theoretical only	Indeterminate	Against
<i>Measles Vaccine</i> ^f			
Encephalopathy	Demonstrated	Indeterminate	Indeterminate
Subacute sclerosing panencephalitis	Demonstrated	Indeterminate	Indeterminate
Residual seizure disorder	Demonstrated	Indeterminate	No data
Sensorineural deafness	Theoretical only	Indeterminate (MMR)	No data
Optic neuritis	Demonstrated	Indeterminate	No data
Transverse myelitis	Demonstrated	Indeterminate	No data
Guillain-Barré syndrome	Demonstrated	Indeterminate	No data
Thrombocytopenia	Demonstrated	Indeterminate (measles) For (MMR)	Indeterminate (measles) No data (MMR)
Insulin-dependent diabetes mellitus	Theoretical only	Indeterminate	Indeterminate

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Vaccine and Adverse Event	Biologic Plausibility ^e	Case Reports, Case Series, and Uncontrolled Observational Studies	Controlled Observational Studies and Controlled Clinical Trials
Anaphylaxis	Theoretical only	For	No data
Death from vaccine-strain viral infection ^e	Demonstrated	For	No data
<i>Mumps Vaccine</i> ^f			
Encephalopathy	Demonstrated	Indeterminate	No data
Aseptic meningitis	Demonstrated	Indeterminate	No data
Residual seizure disorder	Theoretical only	No data	No data
Neuropathy	Theoretical only	No data	No data
Sensorineural deafness	Demonstrated	Indeterminate (MMR)	No data
Insulin-dependent diabetes mellitus	Demonstrated	Indeterminate	Indeterminate
Sterility	Demonstrated	No data	No data
Thrombocytopenia	Demonstrated	Indeterminate	No data
Anaphylaxis	Theoretical only	Indeterminate (MMR)	No data

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TABLE 1-2 Conclusions Based on the Evidence Bearing on Causality

DTP/dT	Measles ^a	Mumps ^a	OPV/IPV ^b	Hepatitis B	<i>H. influenzae</i> type ^b
<i>Category, 1: No Evidence Bearing on a Causal Relation</i>					
		Neuropathy	Transverse myelitis (IPV)		
		Residual seizure disorder	Thrombocytopenia (IPV)		
			Anaphylaxis (IPV)		
<i>Category, 2: The Evidence Is Inadequate to Accept or Reject a Causal Relation</i>					
Residual seizure disorder other than infantile spasms	Encephalopathy	Encephalopathy	Transverse myelitis (OPV)	Guillain-Barré syndrome	Guillain-Barré syndrome
	Subacute sclerosing panencephalitis	Aseptic meningitis			
			Guillain-Barré syndrome (IPV)	Demyelinating diseases of the central nervous system	Transverse myelitis
Demyelinating diseases of the central nervous system	Residual seizure	Sensorineural deafness (MMR)	Death from SIDS ^c		Thrombocytopenia
Mononeuropathy	Sensorineural deafness (MMR)	Insulin-dependent diabetes mellitus		Arthritis	Anaphylaxis
Arthritis	Optic neuritis	Sterility		Death from SIDS ^c	Death from SIDS ^c

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DT/Td/T	Measles ^a	Mumps ^a	OPV/IPV ^b	Hepatitis B	H. influenzae type ^b
Erythema multiforme	Transverse myelitis Guillain-Barré syndrome Thrombocytopenia Insulin-dependent diabetes mellitus	Thrombocytopenia Anaphylaxis ^d			
<i>Category 3: The Evidence Favors Rejection of a Causal Relation</i>					
Encephalopathy ^e					
Infantile spasms (DT only) ^f Death from SIDS (DT only) ^{f,g}					
<i>Category 4: The Evidence Favors Acceptance of a Causal Relation</i>					
Guillain-Barré syndrome ^h Anaphylaxis ^a					
Brachial neuritis ^h					

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DTY/Td/T	Measles ^a	Mumps ^a	OPV/IPV ^b	Hepatitis B	H. influenzae type ^b
<i>Category 5: The Evidence Establishes a Causal Relation</i>					
Anaphylaxis ^b	Thrombocytopenia (MMR)			Poliomyelitis in recipient or contact (OPV)	Anaphylaxis
	Anaphylaxis (MMR) ^d Death from measles vaccine-strain viral infection ^{c,i}		Death from polio vaccine-strain viral infection ^{c,i}		

^a If the data derive from a monovalent preparation, then in the committee's judgment the causal relation extends to multivalent preparations. If the data derive exclusively from MMR, that is so indicated by (MMR). In the absence of any data on the monovalent preparation, in the committee's judgment the causal relation determined for the multivalent preparations does not extend to the monovalent components.

^b For some adverse events, the committee was charged with assessing the causal relation between the adverse event and only oral polio vaccine (OPV) (paralytic and nonparalytic poliomyelitis) or only inactivated polio vaccine (IPV) (anaphylaxis and thrombocytopenia). If the conclusions are different for OPV than for IPV for the other adverse events, that is so noted.

^c This table lists weight-of-evidence determinations only for deaths that are classified as AIDS and deaths that are a consequence of vaccine-strain adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in association with a vaccine-associated adverse event is limited to tetanus-diphtheria toxoid for adult use (Td) and Guillain-Barré syndrome, tetanus toxoid and anaphylaxis, and OPV and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and anaphylaxis, MMR and anaphylaxis, hepatitis B vaccine and anaphylaxis, and H. influenzae type b unconjugated PRP vaccine and early-onset H. influenzae type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details.

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EXECUTIVE SUMMARY

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^d The evidence that establishes a causal relation for anaphylaxis derives from MMR. The evidence regarding monovalent measles vaccine favors acceptance of a causal relation, but are less convincing, mostly because of incomplete documentation of symptoms or the possible attenuation of symptoms by medical intervention.

^e The evidence derives from studies of diphtheria-tetanus toxoid for pediatric use (DT). If the evidence favors rejection of a causal relation between DT and encephalopathy, then in the committee's judgment the evidence favors rejection of a causal relation between Td and tetanus toxoid and encephalopathy.

^f Infantile spasms and SIDS occur only in an age group that receives DT but not Td or tetanus toxoid.

^g The evidence derives mostly from DPT. Because there are supportive data favoring rejection of a causal relation between DT and SIDS as well, if the evidence favors rejection of a causal relation between DPT and SIDS, then in the committee's judgment the evidence favors rejection of a causal relation between DT and SIDS.

^h The evidence derives from tetanus toxoid. If the evidence favors acceptance of (or establishes) a causal relation between tetanus toxoid and an adverse event, then in the committee's judgment the evidence favors acceptance of (or establishes) a causal relation between DT and Td and the adverse event as well.

ⁱ The data come primarily from individuals proven to be immunocompromised.

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NEED FOR RESEARCH AND SURVEILLANCE

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Need for Research and Surveillance

The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern. Although the committee was not charged with proposing specific research investigations, in the course of its reviews additional obvious needs for research and surveillance were identified, and those are briefly described here.

DIPHTHERIA AND TETANUS TOXOIDS

Recent advances in molecular analysis of diphtheria and tetanus toxins make it possible to construct mutant toxins that would be potentially safer, more immunogenic, and more readily purified for use as vaccines. A nontoxic variant of diphtheria toxin (CRM₁₉₇) is already used as a protein carrier molecule in one of the licensed *Haemophilus influenzae* type b polysaccharide-protein conjugate vaccines (see [Chapter 9](#)). If mutant toxin vaccines are more immunogenic than the presently used chemically inactivated toxins, successful immunization might be achieved with fewer doses and fewer adverse events.

The possibility of lot-specific reactions to diphtheria and tetanus toxoids, as has been demonstrated for diphtheria and tetanus toxoids and pertussis vaccine preparations, suggests that studies could be more revealing if the vaccines were tracked by lot.

Exhibit GG

Adverse Effects of Vaccines

Evidence and Causality

Committee to Review Adverse Effects of Vaccines
Board on Population Health and Public Health Practice
Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,
Editors

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*
—Goethe



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Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by **Charles C. J. Carpenter**, The Miriam Hospital, and **Floyd E. Bloom**, The Scripps Research Institute. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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TABLE S-1 Adverse Events and Causality Conclusions Included in the Vaccine Chapters

Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injection-Related Events Chapter 12
Disseminated Oka VZV without Other Organ Involvement		CS							
Disseminated Oka VZV with Subsequent Infection Resulting in Pneumonia, Meningitis, or Hepatitis		CS ^a							
Vaccine Strain Viral Reactivation without Other Organ Involvement		CS							
Vaccine Strain Viral Reactivation with Subsequent Infection Resulting in Meningitis or Encephalitis		CS							
Measles Inclusion Body Encephalitis	CS ^{a,b}								
Encephalitis	I		I		I		I	I	
Encephalopathy	I	I	I		I		I	I	
Infantile Spasms							I		

continued

TABLE S-1 Continued

Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injection-Related Events Chapter 12
Febrile Seizures	CS								
Afebrile Seizures	I								
Seizures		I	I ^c		I		I		
Meningitis	I ^c								
Cerebellar Ataxia		I							
Ataxia	I						I		
Autism	FR						I		
Acute Disseminated Encephalomyelitis	I	I	I	I	I	I	I	I	
Transverse Myelitis	I	I	I	I	I	I	I	I	
Optic Neuritis	I ^c		I ^c		I ^c		I ^c		
Neuromyelitis Optica	I ^c		I		I	I			
Multiple Sclerosis Onset in Adults	I		I		I		I		
Multiple Sclerosis Onset in Children	I				I				
Multiple Sclerosis Relapse in Adults			I		I		I		

Multiple Sclerosis Relapse in Children					I			I
Multiple Sclerosis					I		I	I
First Demyelinating Event in Adults					I			
First Demyelinating Event in Children					I			
Guillain-Barré Syndrome	I	I	I	I	I	I	I	I
Chronic Inflammatory Disseminated Polyneuropathy	I		I	I	I	I	I	I
Opsoclonus Myoclonus Syndrome	I							I
Bell's Palsy			FR	I				I
Brachial Neuritis	I		I		I	I		
Amyotrophic Lateral Sclerosis							I	
Small Fiber Neuropathy		I ^e	I					
Anaphylaxis	CS	CS	CS	I	CS ^d	FA	CS ^e	CS
Chronic Urticaria							I	
Serum Sickness							I	

TABLE S-1 Continued

Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injection-Related Events Chapter 12
Inactivated Influenza Vaccine and Asthma Exacerbation or Reactive Airway Disease Episodes in Children and Adults			FR						
Live Attenuated Influenza Vaccine and Asthma Exacerbation or Reactive Airway Disease Episodes in Children Younger Than 5 Years of Age			I						
Live Attenuated Influenza Vaccine and Asthma Exacerbation or Reactive Airway Disease Episodes in Persons 5 Years of Age or Older			I						
Erythema Nodosum					I ^c				
Systemic Lupus Erythematosus			I		I				
Vasculitis			I		I				
Polyarteritis Nodosa			I		I				

Psoriatic Arthritis						I
Reactive Arthritis						I
Rheumatoid Arthritis						I
Juvenile Idiopathic Arthritis						I
Transient Arthralgia in Women	FA					
Transient Arthralgia in Children	FA					
Transient Arthralgia						I
Chronic Arthralgia in Women	I					
Chronic Arthritis in Women	I					
Chronic Arthropathy in Children	I					
Arthropathy in Men	I					
Arthropathy		I	I			I
Type 1 Diabetes	FR				I	FR
Autoimmune Hepatitis					I	
Myocarditis						I
Pancreatitis						I

continued ↘

TABLE S-1 Continued

Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injection-Related Events Chapter 12
Hepatitis	I								
Thromboembolic Events						I			
Stroke		I ^e	I						
Hypercoagulable States						I			
Myocardial Infarction			I						
Chronic Fatigue Syndrome	I								
Chronic Headache							I		
Fibromyalgia	I		I		I		I		
Sudden Infant Death Syndrome							I		
Hearing Loss	I								
All Cause Mortality			I ^e						
Oculorespiratory Syndrome			FA ^g						
Thrombocytopenia		I							
Immune Thrombocytopenic Purpura							I		
Complex Regional Pain Syndrome									I

Deltoid Bursitis CS

Syncope CS

NOTE: CS = convincingly supports a causal relationship; FA = favors acceptance of a causal relationship; FR = favors rejection of a causal relationship; I = inadequate to accept or reject a causal relationship.

^aThe committee attributes causation to individuals with demonstrated immunodeficiencies.

^bThe committee attributes causation to the measles component of the vaccine.

^cAlthough not originally charged to the committee by the sponsor, the committee considered this adverse event in its review of the literature.

^dThe committee attributes causation to yeast-sensitive individuals.

^eThe committee attributes causation to the tetanus toxoid vaccine. The evidence is inadequate to accept or reject a causal relationship between anaphylaxis and diphtheria toxoid or acellular pertussis vaccine.

^fThe committee attributes causation to the rubella component of the vaccine.

^gThe committee attributes causation to two particular vaccines used in three particular years in Canada.

Exhibit HH

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of the mechanisms and sequence of events that result in vaccine-induced GBS.

DEATH

The committee encourages active and aggressive follow-up of the reports to passive surveillance system of death in association with immunization. This follow-up should be timely and might include elements such as medical records, laboratory tests, and autopsy results. See the section on General Surveillance and Epidemiologic Studies for elaboration.

SIMULTANEOUS ADMINISTRATION OF MORE THAN ONE VACCINE

The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously. This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use. Both pre- and postmarketing research should address the issue.

RISK-MODIFYING FACTORS

The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not. When it is clear that a vaccine can cause a specific adverse event, research should be encouraged to elucidate the factors that put certain people at risk for that adverse reaction.

GENERAL SURVEILLANCE AND EPIDEMIOLOGIC STUDIES

Postmarketing surveillance of licensed vaccines in the United States depends upon voluntary reporting. Large numbers of alleged adverse events are reported to the Vaccine Adverse Event Reporting System (VAERS) of the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration. The committee found, however, that follow-up of serious adverse events was often incomplete, and the reported event was often not confirmed because of insufficient clinical, laboratory, or pathologic data. The committee suggests that, in the least, research should be conducted on the performance of passive reporting systems like VAERS. What is the quality and completeness of the information supplied? Can the reports received be used to estimate the true risk of vaccine-induced adverse events? Perhaps most important, how well does the surveillance system detect new

Exhibit I

bin and its cofactor thrombin-thrombomodulin (Rezaie, 2010). Activated protein C functions as an anticoagulant by proteolytically degrading procoagulant cofactors essential for the generation of thrombin (Rezaie, 2010). The cofactor protein S enhances effects of activated protein C (Anderson and Weitz, 2010). In addition, the serine protease inhibitor antithrombin regulates the coagulation cascade by inactivating thrombin as well as other enzymes in the cascade (Rodgers, 2009).

In individuals with inherited (e.g., antithrombin deficiency, Factor V Leiden) or acquired (e.g., obesity, pregnancy) hypercoagulable states, the function of the enzymes involved in the aforementioned coagulation cascade and its regulation are altered or deficient, leading to excessive coagulability (Anderson and Weitz, 2010). Excessive coagulation can contribute to the development of thrombosis, myocardial infarction, and stroke (Anderson and Weitz, 2010).

INCREASED SUSCEPTIBILITY

Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact as suggested graphically in Figure 3-1.

Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not. Moreover, the occurrence of the adverse event is often the first sign of the underlying condition that confers susceptibility.

The best-understood vaccine-associated adverse effect is the occurrence of invasive disease (such as meningoencephalitis and arthritis) caused by the vaccine virus itself in individuals with an acquired or genetic immunodeficiency who receive live vaccines such as VZV, MMR, and oral polio vaccine. Although the incidence of such infections may decrease with the introduction of newborn screening for severe combined immunodeficiency, the occurrence of vaccine-related disease can be the trigger that leads to the recognition of immunodeficiency (Galea et al., 2008; Ghaffar et al., 2000; Kramer et al., 2001; Levy et al., 2003). Invasive disease may also occur by viral reactivation in individuals who previously received these vaccines while healthy, but who subsequently become immunocompromised, for example, as a result of chemotherapy should they later develop cancer or leukemia (Chan et al., 2007; Levin et al., 2003). Not all individuals who suffer invasive disease have demonstrated recognized immune deficiencies, even when vaccine virus is recovered from the patient (Iyer et al.,

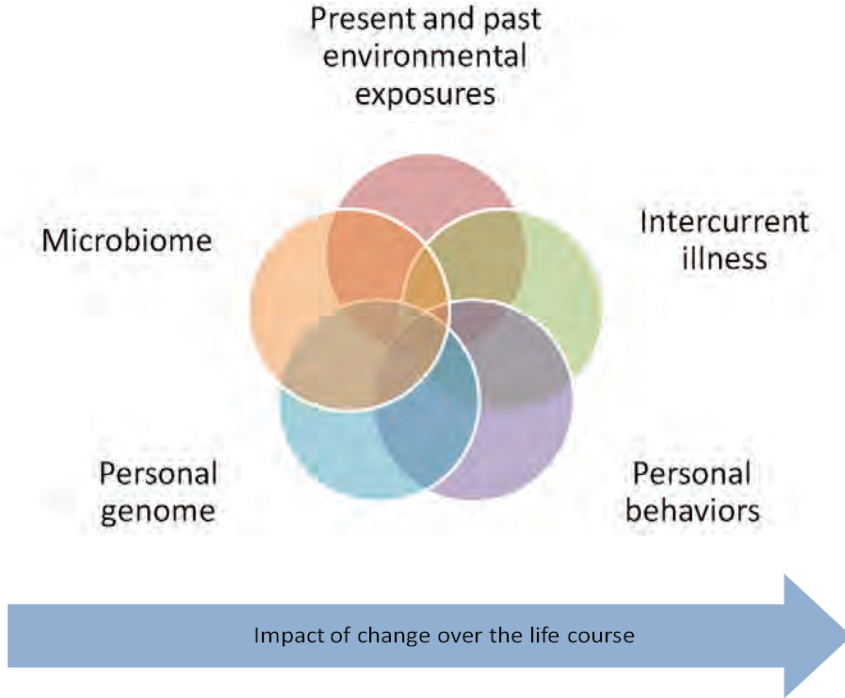


FIGURE 3-1 Present and past environmental exposures.

2009; Levin et al., 2008). This leads to two hypotheses: either immunocompetent individuals can acquire invasive disease from vaccine virus, or further evaluation of these patients would reveal previously unrecognized immunodeficiencies.

Many adverse events appear to be immune-mediated. Anaphylaxis is an obvious example of this. In some patients who experience anaphylaxis, the triggering antigen can be identified with follow-up testing. Known triggering antigens include egg and gelatin. But even when the triggering antigen such as egg or gelatin is known, it is not clear why some people develop anaphylaxis while the vast majority does not. Proposed mechanisms for other immune-mediated adverse responses are many, including molecular mimicry, development of immune complexes, inappropriate cytokine responses, antigen persistence, and epitope spreading, as described above. Here, evidence of predisposing factors to adverse effects from vaccines is beginning to emerge. Some genetic variants that affect immune response have been identified. Reif et al. (2009) demonstrated that genetic variants in ICAM-1, CSF-3, and IL-4 are associated with more severe adverse effects

from the highly reactogenic vaccine for smallpox. Finally, rechallenge cases (those in which a person suffered a particular adverse event after each administration of the same vaccine) also suggest a role for an altered immune response. As noted above, much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.

Age can also affect susceptibility to adverse responses to vaccines because physiological development, particularly of the immune and nervous systems, continues throughout much or all of life. Some hypothesize so-called *critical periods* in which adverse reactions to a range of exposures are more likely to occur (IOM, 2006). Young children are more likely than are older children to develop febrile convulsions (Waruiru and Appleton, 2004). This type of rationale led the Japanese three decades ago to delay immunization with whole cell pertussis vaccine until children reached 2 years of age (Gangarosa et al., 1998). Gender can also be a factor. Females, for example, experience less local reactogenicity than males to smallpox vaccine (Talbot et al., 2004) but increased reactogenicity compared to males to anthrax vaccine (Pittman, 2002).

In some metabolically vulnerable children, receiving vaccines may be the largely nonspecific “last straw” that leads these children to reveal their underlying genotype. It was recently discovered that a large majority of children who developed encephalopathy after receiving whole cell pertussis vaccine have mutations in *SCN1A*, which are associated with Dravet syndrome or severe myoclonic epilepsy of childhood (Berkovic et al., 2006; McIntosh et al., 2010). While it seems likely that the vaccine triggered symptoms in these children by causing high fever, the particular vaccine antigens do not appear to alter the course of the disease. Rather, the ensuing phenotype could and probably would have been precipitated by multiple other fever-inducing triggers (McIntosh et al., 2010; Wiznitzer, 2010). Similarly, Yang et al. (2006) reported a series of seven cases in which children with undiagnosed or inadequately managed metabolic or endocrine disorders suffered acute metabolic crises within hours after administration of a variety of immunizations. Two of these children had adrenal hyperplasia and responded to administration of IV fluid and glucocorticoids.

This list of factors that are known to confer susceptibility is by no means definitive or exhaustive. Rather, we hypothesize that continued study of alleged vaccine-related injuries, the committee informed by epidemiologic studies that identify vulnerable populations and exploration of underlying mechanisms of susceptibility, will provide greater insight into these and other mechanisms and will identify more factors that contribute to vaccine susceptibility.

Exhibit JJ

December 8, 2014 Approval Letter - MMR II

SUPPLEMENT APPROVAL LETTER

Our STN: BL 101069/5577

Merck Sharp & Dohme Corp.
Attention: Donna Zacholski
P.O. Box 1000, UG2D-68
North Wales, PA 19454-1099

Dear Ms. Zacholski:

We have approved your request to supplement your biologics license application for Measles, Mumps, and Rubella Virus Vaccine Live (MMR-II®) manufactured in your West Point, PA facility, to add the term "transverse myelitis" to the Adverse Reactions section of the package insert and to update the patient package insert to add the term "difficulty walking," based on post-marketing adverse event reports.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at: <http://www.fda.gov/For-Industry/DataStandards/StructuredProductLabeling/default.htm> (<http://www.fda.gov/For-Industry/DataStandards/StructuredProductLabeling/default.htm>). Information on submitting SPL files using eLIST may be found in the guidance for industry titled, "SPL Standard for Content of Labeling Technical Qs and As at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf> (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>).

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling (/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf)

Resources for You

- **Measles, Mumps and Rubella Virus Vaccine, Live**
(/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094050.htm)

More in Approved Products

(/BiologicsBloodVaccines/Vaccines/ApprovedProducts/default.htm)



SUPPLEMENT APPROVAL

Our STN: BL 101069/5650

Merck Sharp & Dohme Corp.
Attention: James J. Kollmar, M.D.
351 N. Sumneytown Pike
P.O. Box 1000
UG2D-68
North Wales, PA 19454

May 16, 2017

Dear Dr. Kollmar:

We have approved your request dated November 11, 2016, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Measles, Mumps and Rubella Virus Vaccine Live to revise the package insert to add the terms "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" to the Adverse Reaction section based on post-marketing reports.

We hereby approve the draft package insert labeling submitted under amendment 101069/5650.1, dated April 27, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to BLA 101069 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Page 2 – STN 101069/5650 – James J. Kollmar, M.D.

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes [this][these] change(s).

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Exhibit KK

VACCINE INFORMATION STATEMENT

MMR (Measles, Mumps, and Rubella) Vaccine: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Measles, mumps, and rubella are viral diseases that can have serious consequences. Before vaccines, these diseases were very common in the United States, especially among children. They are still common in many parts of the world.

Measles

- Measles virus causes symptoms that can include fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body.
- Measles can lead to ear infections, diarrhea, and infection of the lungs (pneumonia). Rarely, measles can cause brain damage or death.

Mumps

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears on one or both sides.
- Mumps can lead to deafness, swelling of the brain and/or spinal cord covering (encephalitis or meningitis), painful swelling of the testicles or ovaries, and, very rarely, death.

Rubella (also known as German Measles)

- Rubella virus causes fever, sore throat, rash, headache, and eye irritation.
- Rubella can cause arthritis in up to half of teenage and adult women.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases can easily spread from person to person. Measles doesn't even require personal contact. You can get measles by entering a room that a person with measles left up to 2 hours before.

Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2 MMR vaccine

Children should get 2 doses of MMR vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. This can provide temporary protection from measles infection, but will not

give permanent immunity. The child should still get 2 doses at the recommended ages for long-lasting protection.

Adults might also need MMR vaccine. Many adults 18 years of age and older might be susceptible to measles, mumps, and rubella without knowing it.

A third dose of MMR might be recommended in certain mumps outbreak situations.

There are no known risks to getting MMR vaccine at the same time as other vaccines.

There is a combination vaccine called **MMRV** that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- **Has any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of MMR vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Is pregnant, or thinks she might be pregnant.** Pregnant women should wait to get MMR vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting MMR vaccine.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a parent, brother, or sister with a history of immune system problems.**
- **Has ever had a condition that makes them bruise or bleed easily.**
- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone MMR vaccination for 3 months or more.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

- **Has tuberculosis.**
- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.
- **Is not feeling well.** A mild illness, such as a cold, is usually not a reason to postpone a vaccination. Someone who is moderately or severely ill should probably wait. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Getting MMR vaccine is much safer than getting measles, mumps, or rubella disease. Most people who get MMR vaccine do not have any problems with it.

After MMR vaccination, a person might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site
- Swelling of glands in the cheeks or neck

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

Moderate events:

- Seizure (jerking or staring) often associated with fever
- Temporary pain and stiffness in the joints, mostly in teenage or adult women
- Temporary low platelet count, which can cause unusual bleeding or bruising
- Rash all over body

Severe events occur very rarely:

- Deafness
- Long-term seizures, coma, or lowered consciousness
- Brain damage

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your health care provider.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS *does not give medical advice.*

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement MMR Vaccine

2/12/2018

42 U.S.C. § 300aa-26

Office use only



Exhibit LL

\$101 Million Award for Encephalopathy from MMR Vaccine

(July 17th, 2018. SARASOTA, FL) – MCT Law attorneys negotiated a \$101 million settlement for an infant who suffered a severe reaction to the MMR vaccine.

O.R.* was a one-year-old healthy baby girl who was already walking and climbing. On February 13, 2013, she received vaccinations for Measles Mumps Rubella (MMR), Hepatitis A, Haemophilus Influenzae type B (Hip), Prevnar (pneumonia), and Varicella (chickenpox). That evening, the mother noticed baby O.R. was irritable and feverish. After a call to the pediatrician, the doctor advised Mom to give her Tylenol and Benadryl. The fever continued for several days and on the evening before her scheduled pediatrician visit, O.R. began having severe seizures. She was rushed to the emergency room. Baby O.R. went into cardiac and respiratory arrest and doctors placed her on a ventilator.

The seizures and cardiac arrest left O.R. with a severe brain injury, [encephalopathy](#), cortical vision impairment, truncal hypotonia (low muscle tone), and kidney failure. After months of treatment at the hospital, baby O.R. finally went home, but her disabilities require specialized medical care and supervision around the clock for the rest of her life.

The \$101 million-dollar settlement pays for the child's constant high-level medical care needed for the rest of her life. The family received a lump sum of \$1 million dollars to cover the immediate costs of medical bills and expenses. The rest will be paid out through an annuity over the child's lifetime.

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-119V

Filed: November 20, 2017

UNPUBLISHED

██████████ on behalf of
██████████ a minor child,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Damages Decision Based on Proffer;
Measles Mumps Rubella (MMR)
Vaccine; Encephalopathy

*Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.*

DECISION AWARDING DAMAGES¹

Dorsey, Chief Special Master:

On January 27, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that ██████████ was diagnosed with encephalopathy following receipt of Hepatitis A, Haemophilus influenza type B, measles, mumps and rubella (MMR), Prevnar, and varicella vaccinations on February 13, 2013. Petition at 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

On July 18, 2016, a ruling on entitlement was issued, finding petitioner entitled to compensation for ██████████’s encephalopathy injury. On November 17, 2017, respondent filed a proffer on award of compensation (“Proffer”). Respondent proffers that, based upon her review of the evidence of record, petitioner should be awarded:

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

- A. A lump sum in the amount of \$1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of [REDACTED]
- B. A lump sum in the amount of \$1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of [REDACTED] for the benefit of [REDACTED]
- C. A lump sum payment of \$278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien; and
- D. An amount sufficient to purchase the annuity contract described above in section II.D.

In the Proffer, respondent represented that petitioner agrees with the proffered award. Based on the record as a whole, the undersigned finds that petitioner is entitled to an award as stated in the Proffer.

Pursuant to the terms stated in the attached Proffer, **the undersigned awards petitioner:**

- A. A lump sum in the amount of \$1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of [REDACTED]**
- B. A lump sum in the amount of \$1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of [REDACTED] for the benefit of [REDACTED]**
- C. A lump sum payment of \$278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien payable jointly to petitioner and**

**Oklahoma Health Care Authority
P.O. Box 18497
Oklahoma City, Oklahoma 73154
Attn: Susan L. Eads
c/o Legal Unit
OHCA Case No: 502137**

Petitioner agrees to endorse this payment to the State of Oklahoma.; and

- D. An amount sufficient to purchase the annuity contract described in Proffer Section II.D.**

This amount represents compensation for all damages that would be available under § 300aa-15(a).

The clerk of the court is directed to enter judgment in accordance with this decision.³

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master

³ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

)	
██████████ on behalf of)	
██████████ a minor child,)	
)	
Petitioner,)	
)	
v.)	No. 16-119V
)	Chief Special Master Dorsey
SECRETARY OF THE DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

RESPONDENT'S PROFFER ON AWARD OF COMPENSATION

I. Items of Compensation

A. Life Care Items

The respondent engaged life care planner, M. Virginia NeSmith Walton, RN, MSN, FNP, CNCLP, and petitioner engaged Lynne Trautwein, MSN, RN, CCM, CMAC, CNLCP, to provide an estimation of ██████████'s future vaccine-injury related needs. For the purposes of this proffer, the term "vaccine related" is as described in the Chief Special Master's Ruling on Entitlement, filed July 18, 2016. All items of compensation identified in the life care plan are supported by the evidence, and are illustrated by the chart entitled Appendix A: Items of Compensation for ██████████ attached hereto as Tab A.¹ Respondent proffers that ██████████ should be

¹ The chart at Tab A illustrates the annual benefits provided by the life care plan. The annual benefit years run from the date of judgment up to the first anniversary of the date of judgment, and every year thereafter up to the anniversary of the date of judgment.

awarded all items of compensation set forth in the life care plan and illustrated by the chart attached at Tab A. Petitioner agrees.

B. Lost Future Earnings

The parties agree that based upon the evidence of record, [REDACTED] will not be gainfully employed in the future. Therefore, respondent proffers that [REDACTED] should be awarded lost future earnings as provided under the Vaccine Act, 42 U.S.C. § 300aa-15(a)(3)(B). Respondent proffers that the appropriate award for [REDACTED]'s lost future earnings is \$793,951.66. Petitioner agrees.

C. Pain and Suffering

Respondent proffers that [REDACTED] should be awarded \$250,000.00 in actual pain and suffering. See 42 U.S.C. § 300aa-15(a)(4). Petitioner agrees.

D. Past Unreimbursable Expenses

Petitioner represents that he has not incurred past unreimbursable expenses related to [REDACTED]'s vaccine-related injury.

E. Medicaid Lien

Respondent proffers that [REDACTED] should be awarded funds to satisfy a State of Oklahoma lien in the amount of \$278,476.84, which represents full satisfaction of any right of subrogation, assignment, claim, lien, or cause of action the State of Oklahoma may have against any individual as a result of any Medicaid payments the State of Oklahoma has made to or on behalf of [REDACTED] from the date of her eligibility for benefits through the date of judgment in this case as a result of her vaccine-related injury suffered on or about February 13, 2013, under Title XIX of the Social Security Act.

II. Form of the Award

The parties recommend that the compensation provided to [REDACTED] should be made through a combination of lump sum payments and future annuity payments as described below, and request that the Chief Special Master's decision and the Court's judgment award the following:²

A. A lump sum payment of \$1,191,475.29, representing trust seed funds consisting of the present year cost of compensation for residential facility expenses in Compensation Year 2062 through Compensation Year 2066 (\$949,000.00) and life care expenses in the first year after judgment (\$242,475.29), in the form of a check payable to Regions Bank, as Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] as set forth in Appendix A: Items of Compensation for [REDACTED]

B. A lump sum payment of \$1,043,951.66, representing compensation for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00), in the form of a check payable to petitioner as guardian(s)/conservator(s) of [REDACTED] for the benefit of [REDACTED]. No payments shall be made until petitioner provides respondent with documentation establishing that he has been appointed as the guardian(s)/conservator(s) of [REDACTED]'s estate. If petitioner is not authorized by a court of competent jurisdiction to serve as guardian of the estate of [REDACTED] any such payment shall be made to the party or parties appointed by a court of competent jurisdiction to serve as

² Should [REDACTED] die prior to entry of judgment, the parties reserve the right to move the Court for appropriate relief. In particular, respondent would oppose any award for future medical expenses, future lost earnings, and future pain and suffering.

guardian(s)/conservator(s) of the estate of [REDACTED] upon submission of written documentation of such appointment to the Secretary.

C. A lump sum payment of \$278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien, payable jointly to petitioner and

Oklahoma Health Care Authority
P.O. Box 18497
Oklahoma City, Oklahoma 73154
Attn: Susan L. Eads
c/o Legal Unit
OHCA Case No: 502137

Petitioner agrees to endorse this payment to the State of Oklahoma.

D. An amount sufficient to purchase the annuity contract,³ subject to the conditions described below, that will provide payments for the life care items contained in the life care plan, as illustrated by the chart at Tab A attached hereto, paid to the life insurance company⁴ from which the annuity will be purchased.⁵ Compensation for Year Two (beginning on the first

³ In respondent's discretion, respondent may purchase one or more annuity contracts from one or more life insurance companies.

⁴ The Life Insurance Company must have a minimum of \$250,000,000 capital and surplus, exclusive of any mandatory security valuation reserve. The Life Insurance Company must have one of the following ratings from two of the following rating organizations:

- a. [REDACTED] Best Company: A++, A+, A+g, A+p, A+r, or A+s;
- b. Moody's Investor Service Claims Paying Rating: Aa3, Aa2, Aa1, or Aaa;
- c. Standard and Poor's Corporation Insurer Claims-Paying Ability Rating: AA-, AA, AA+, or AAA;
- d. Fitch Credit Rating Company, Insurance Company Claims Paying Ability Rating: AA-, AA, AA+, or AAA.

⁵ Petitioner authorizes the disclosure of certain documents filed by the petitioner in this case consistent with the Privacy Act and the routine uses described in the National Vaccine Injury Compensation Program System of Records, No. 09-15-0056.

anniversary of the date of judgment) and all subsequent years shall be provided through respondent's purchase of an annuity, which annuity shall make payments directly to the trustee only so long as [REDACTED] is alive at the time a particular payment is due. At the Secretary's sole discretion, the periodic payments may be provided to the trustee in monthly, quarterly, annual or other installments. The "annual amounts" set forth in the chart at Tab A describe only the total yearly sum to be paid to the trustee and do not require that the payment be made in one annual installment.

1. Growth Rate

Respondent proffers that a four percent (4%) growth rate should be applied to all non-medical life care items, and a five percent (5%) growth rate should be applied to all medical life care items. Thus, the benefits illustrated in the chart at Tab A that are to be paid through annuity payments should grow as follows: four percent (4%) compounded annually from the date of judgment for non-medical items, and five percent (5%) compounded annually from the date of judgment for medical items. Petitioner agrees.

2. Life-Contingent Annuity

The trustee will continue to receive the annuity payments from the Life Insurance Company only so long as [REDACTED] is alive at the time that a particular payment is due. Written notice shall be provided to the trustee and the Secretary of Health and Human Services and the Life Insurance Company within twenty (20) days of [REDACTED]'s death.

3. Guardianship

No payments shall be made until petitioner provides respondent with documentation establishing that he has been appointed as the guardian of [REDACTED]'s estate. If petitioner is not authorized by a

court of competent jurisdiction to serve as guardian of the estate of [REDACTED] any such payment shall be made to the party or parties appointed by a court of competent jurisdiction to serve as guardian(s)/conservator(s) of the estate of [REDACTED] upon submission of written documentation of such appointment to the Secretary.

III. Summary of Recommended Payments Following Judgment

- | | | |
|----|---|-----------------------|
| A. | Lump Sum paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of [REDACTED] | \$1,191,475.29 |
| B. | Lump Sum paid to the court-appointed guardian(s)/conservator(s) of the estate of [REDACTED] for the benefit of [REDACTED] | \$1,043,951.66 |
| C. | Medicaid Lien: | \$ 278,476.84 |
| D. | An amount sufficient to purchase the annuity contract described above in section II. D. | |

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

C. SALVATORE D’ALESSIO
Acting Director
Torts Branch, Civil Division

CATHARINE E. REEVES
Deputy Director
Torts Branch, Civil Division

HEATHER L. PEARLMAN
Assistant Director
Torts Branch, Civil Division

/s/Camille M. Collett
CAMILLE M. COLLETT
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Torts Branch, Civil Division
U. S. Department of Justice
P.O. Box 146, Benjamin Franklin Station
Washington, D.C. 20044-0146
Direct dial: (202) 616-4098

Dated: November 17, 2017

NYSCEF DOC. NO. 41		Lump Sum					RECEIVED	NYSCEF:	08/24/2020	
ITEMS OF COMPENSATION	G.R.	*	Compensation Year 1	Compensation Year 2	Compensation Year 3	Compensation Year 4	Compensation Year 5	Compensation Year 6	Compensation Year 7	Compensation Year 8
			2017	2018	2019	2020	2021	2022	2023	2024
Nebulizer	5%	*								
Disposable Nebulizer Supplies	5%	*								
Omeprazol	4%		212.92	212.92	212.92	212.92	212.92	212.92	212.92	212.92
Kenalog	5%	*								
Pediasure Peptide	4%	*								
Pediasure	4%	*								
Real Food Blends	4%		4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*								
Gastrostomy Tube Supplies	4%	*								
Diapers	4%		593.18	593.18	593.18	593.18	593.18	593.18	593.18	593.18
Gloves	4%		255.21	255.21	255.21	255.21	255.21	255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33	156.33	156.33	156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71	127.71	127.71	127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97	83.97	83.97	83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00	99.00	99.00	99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98	36.98	36.98	36.98	36.98	36.98
Physical Therapy	4%	*	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00
Mileage: Physical Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Occupational Therapy	4%		4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00
Mileage: Occupational Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Speech Therapy	4%		4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00
Mileage: Speech Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Aug Comm Evaluation	4%	*	500.00	500.00	500.00	500.00	500.00	500.00	500.00	500.00
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Special Needs Camp	4%					300.00	300.00	300.00	300.00	300.00
Overnight Camp	4%					325.00	325.00	325.00	325.00	325.00
Mileage: Camp	4%					68.17	68.17	68.17	68.17	68.17
Wheelchair	4%	*								
Sit & Stander	4%	*								
Shower Chair	4%						300.00	50.00	50.00	50.00
Kid Walk	4%					5,000.00				
Hoyer Lift	4%	*								
Lift Slings	4%						68.00	68.00	68.00	68.00

ITEMS OF COMPENSATION	G.R.	*	Lump Sum							
			Compensation Year 1	Compensation Year 2	Compensation Year 3	Compensation Year 4	Compensation Year 5	RECEIVED Compensation Year 6	NYSCEF: Compensation Year 7	08/24/2020 Compensation Year 8
			2017	2018	2019	2020	2021	2022	2023	2024
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%		1,337.67					1,337.67		
Rehab Equipment	4%		800.00					800.00		
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%								23.99	
iPad	4%		799.00					799.00		
iPad Case	4%		19.95					19.95		
Attendant Care	4%		93,960.00	93,960.00	93,960.00	100,440.00	100,440.00	100,440.00	100,440.00	100,440.00
Respite Care	4%		7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00
McCarty Cntr	4%		1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Attendant Care and Trust Seed	4%		949,000.00							
Ancillary Services-Housekeeping	4%									
Home Mods	4%		73,768.00							
Accessible Van	4%		28,500.00							
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings			793,951.66							
Pain and Suffering			250,000.00							
Medicaid Lien			278,476.84							
Annual Totals			2,513,903.79	134,670.67	134,633.27	146,806.44	139,226.44	142,551.06	139,368.43	139,344.44

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.

Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.

As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] for trust seed funds (\$949,000.00) and Year 1 life care expenses (\$242,475.29): \$1,191,475.29.

As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/conservator(s) of [REDACTED] for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00): \$1,043,951.66.

As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: \$278,476.84.

Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.

Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.

Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

NYSCEF DOC. NO. 41

ITEMS OF COMPENSATION	G.R.	*	Compensation	Compensation	Compensation	Compensation	Compensation	RECEIVED	NYSCEF	08/24/2020
			Year 9	Year 10	Year 11	Year 12	Year 13	Compensation	Compensation	Compensation
			2025	2026	2027	2028	2029	2030	2031	2032
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%				1,337.67					1,337.67
Rehab Equipment	4%				800.00					800.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%							34.90	3.49	3.49
iPad	4%				799.00					799.00
iPad Case	4%				19.95					19.95
Attendant Care	4%		155,520.00	155,520.00	155,520.00	155,520.00	155,520.00	155,520.00	157,140.00	157,140.00
Respite Care	4%		7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00
McCarty Cntr	4%		1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Attendant Care and Trust Seed	4%									
Ancillary Services-Housekeeping	4%					1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%									
Accessible Van	4%				28,500.00					
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			192,159.40	197,159.40	223,616.02	193,797.40	193,782.44	193,817.34	187,172.86	200,289.48

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.

Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.

As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] for trust seed funds (\$949,000.00) and Year 1 life care expenses (\$242,475.29): \$1,191,475.29.

As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/conservator(s) of [REDACTED] for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00): \$1,043,951.66.

As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: \$278,476.84.

Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.

Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.

Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 17	Compensation Year 18	Compensation Years 19-20	Compensation Year 21	Compensation Year 22	RECEIVED Compensation Year 23	NYSCEF: Compensation Year 24	08/24/2020 Compensation Year 25
			2033	2034	2035-2036	2037	2038	2039	2040	2041
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%					1,337.67	267.53	267.53	267.53	267.53
Rehab Equipment	4%					800.00	160.00	160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49	3.49	3.49	3.49	3.49	3.49
iPad	4%					799.00	159.80	159.80	159.80	159.80
iPad Case	4%					19.95	3.99	3.99	3.99	3.99
Attendant Care	4%		157,140.00							
Respite Care	4%		7,560.00							
McCarty Cntr	4%		1,000.00							
Attendant Care and Trust Seed	4%			189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%			73,768.00						
Accessible Van	4%					28,500.00	2,850.00	2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			192,248.26	290,116.26	216,348.26	247,832.24	224,953.62	220,950.99	221,217.63	221,436.39

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.

Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.

As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] for trust seed funds (\$949,000.00) and Year 1 life care expenses (\$242,475.29): \$1,191,475.29.

As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of [REDACTED] for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00): \$1,043,951.66.

As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: \$278,476.84.

Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.

Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.

Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 26	Compensation Year 27	Compensation Year 28	Compensation Year 29	Compensation Year 30	RECEIVED Compensation Year 31	NYSCEF: Compensation Year 32	08/24/2020 Compensation Years 33-45
			2042	2043	2044	2045	2046	2047	2048	2049-2061
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%		267.53	267.53	267.53	267.53	267.53	267.53	267.53	267.53
Rehab Equipment	4%		160.00	160.00	160.00	160.00	160.00	160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49	3.49	3.49	3.49	3.49	3.49
iPad	4%		159.80	159.80	159.80	159.80	159.80	159.80	159.80	159.80
iPad Case	4%		3.99	3.99	3.99	3.99	3.99	3.99	3.99	3.99
Attendant Care	4%									
Respite Care	4%									
McCarty Cntr	4%									
Attendant Care and Trust Seed	4%		189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%									
Accessible Van	4%		2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			221,545.83	221,709.87	221,874.03	221,976.51	222,085.95	222,140.67	222,195.27	217,146.15

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.

Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.

As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] for trust seed funds (\$949,000.00) and Year 1 life care expenses (\$242,475.29): \$1,191,475.29.

As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of [REDACTED] for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00): \$1,043,951.66.

As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: \$278,476.84.

Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.

Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.

Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

ITEMS OF COMPENSATION	G.R.	*	Compensation Years 46-50	Compensation Years 51-60	Compensation Years 61-Life
			2062-2066	2067-2076	2077-Life
BCBS Premium	5%				
BCBS MOP	5%				
Medicare Part A Deductible	5%		1,316.00	1,316.00	
Medicare Part B Premium	5%		1,608.00	1,608.00	1,608.00
Medicare Part B Deductible	5%		183.00	183.00	183.00
Medigap	5%		3,147.00	3,147.00	1,707.48
Medicare Part D	5%		406.00	406.00	406.00
Primary Care Physician	5%	*			
Mileage: PCP	4%		1.36	1.36	1.36
Neurologist	5%	*			
Mileage: Neurologist	4%		10.54	10.54	10.54
Neuro Ophthalmologist	5%	*			
Mileage: Neuro Ophthalmologist	4%		74.80	74.80	74.80
Nephrology	5%	*			
Mileage: Nephrology	4%		74.80	74.80	74.80
Gastroenterologist	5%	*			
Mileage: Gastroenterologist	4%		7.82	7.82	7.82
General Surgery	5%	*			
Mileage: General Surgery	4%		9.18	9.18	9.18
Orthopedic Surgery	5%	*			
Mileage: Orthopedic Surgery	4%				
PM&R	5%	*			
Mileage: PM&R	4%		37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45
X-rays	5%	*			
Blood Work	5%	*			
Mileage: Blood Work	4%		4.08	4.08	4.08
Emergency Room	5%	*			
Care Management	4%		5,160.00	5,160.00	5,160.00
Lactulose	5%	*			
Ciprodex Otic	5%	*			
Keppra	5%	*			
Epaned Oral	5%	*			

ITEMS OF COMPENSATION	G.R.	*	Compensation Years 46-50	Compensation Years 51-60	Compensation Years 61-Life
			2062-2066	2067-2076	2077-Life
Nebulizer	5%	*			
Disposable Nebulizer Supplies	5%	*			
Omeprazol	4%		212.92	212.92	212.92
Kenalog	5%	*			
Pediasure Peptide	4%	*			
Pediasure	4%	*			
Real Food Blends	4%		4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*			
Gastrostomy Tube Supplies	4%	*			
Diapers	4%		2,762.14	2,762.14	2,762.14
Gloves	4%		255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98
Physical Therapy	4%	*			
Mileage: Physical Therapy	4%		25.50	25.50	25.50
Occupational Therapy	4%				
Mileage: Occupational Therapy	4%				
Speech Therapy	4%				
Mileage: Speech Therapy	4%				
Aug Comm Evaluation	4%	*			
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00
Special Needs Camp	4%				
Overnight Camp	4%				
Mileage: Camp	4%				
Wheelchair	4%	*			
Sit & Stander	4%	*			
Shower Chair	4%		50.00	50.00	50.00
Kid Walk	4%		833.33	833.33	833.33
Hoyer Lift	4%	*			
Lift Slings	4%		68.00	68.00	68.00

ITEMS OF COMPENSATION	G.R.	*	Compensation	Compensation	Compensation
			Years 46-50	Years 51-60	Years 61-Life
			2062-2066	2067-2076	2077-Life
AFOs	4%	*			
Orthotic Shoes	4%		600.00	600.00	600.00
Tumblefoam Chair	4%		267.53	267.53	267.53
Rehab Equipment	4%		160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49
iPad	4%		159.80	159.80	159.80
iPad Case	4%		3.99	3.99	3.99
Attendant Care	4%				
Respite Care	4%				
McCarty Cntr	4%				
Attendant Care and Trust Seed	4%		-	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00
Home Mods	4%				
Accessible Van	4%		2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00
Lost Future Earnings					
Pain and Suffering					
Medicaid Lien					
Annual Totals			27,346.15	217,146.15	214,390.63

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.

Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.

As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of [REDACTED] for trust seed funds (\$949,000.00) and Year 1 life care expenses (\$242,475.29): \$1,191,475.29.

As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of [REDACTED] for lost future earnings (\$793,951.66) and pain and suffering (\$250,000.00): \$1,043,951.66.

As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: \$278,476.84.

Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.

Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.

Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

Exhibit MM

Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis

Kumanan Wilson^{1,2,3,4*}, Steven Hawken², Jeffrey C. Kwong⁵, Shelley Deeks⁶, Natasha S. Crowcroft⁶, Carl Van Walraven^{1,2,3}, Beth K. Potter^{2,3}, Pranesh Chakraborty^{4,8}, Jennifer Keelan⁷, Michael Pluscauskas⁴, Doug Manuel^{2,3,9}

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Abstract

Background: Live vaccines have distinct safety profiles, potentially causing systemic reactions one to 2 weeks after administration. In the province of Ontario, Canada, live MMR vaccine is currently recommended at age 12 months and 18 months.

Methods: Using the self-controlled case series design we examined 271,495 12 month vaccinations and 184,312 18 month vaccinations to examine the relative incidence of the composite endpoint of emergency room visits or hospital admissions in consecutive one day intervals following vaccination. These were compared to a control period 20 to 28 days later. In a post-hoc analysis we examined the reasons for emergency room visits and the average acuity score at presentation for children during the at-risk period following the 12 month vaccine.

Results: Four to 12 days post 12 month vaccination, children had a 1.33 (1.29–1.38) increased relative incidence of the combined endpoint compared to the control period, or at least one event during the risk interval for every 168 children vaccinated. Ten to 12 days post 18 month vaccination, the relative incidence was 1.25 (95%, 1.17–1.33) which represented at least one excess event for every 730 children vaccinated. The primary reason for increased events was statistically significant elevations in emergency room visits following all vaccinations. There were non-significant increases in hospital admissions. There were an additional 20 febrile seizures for every 100,000 vaccinated at 12 months.

Conclusions: There are significantly elevated risks of primarily emergency room visits approximately one to two weeks following 12 and 18 month vaccination. Future studies should examine whether these events could be predicted or prevented.

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Competing Interests: The authors have declared that no competing interests exist.

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Introduction

The measles, mumps and rubella (MMR) have been used extensively in children and have been demonstrated to be safe and effective in preventing disease [1]. However, because it is a live vaccine the MMR vaccine has the potential to cause adverse events one to 2 weeks following vaccination [2]. Most reactions to this vaccine will be mild with fevers occurring in 5 to 15% and rashes in 5% [3]. More serious reactions are extremely rare and may not be identified during pre-licensure trials [4]. Post market surveillance has identified an incidence of febrile seizures following the MMR vaccine

of 25 to 34 per 100 000 vaccinated and a two to three-fold increased relative risk [5,6]. However, at a population level, mass exposures to a vaccine with a rare side effect profile could have detectable important population level effects. No study has examined the impact on aggregate health service utilization following the MMR vaccination.

In the province of Ontario, Canada, the MMR and meningococcal C vaccines are currently recommended at 12 months of age and a second dose of MMR vaccine along with a booster dose of pentavalent (diphtheria, acellular pertussis, tetanus, polio and *Haemophilus influenzae* type b) vaccine is recommended at 18 months of age. We sought to examine the population wide effects of these

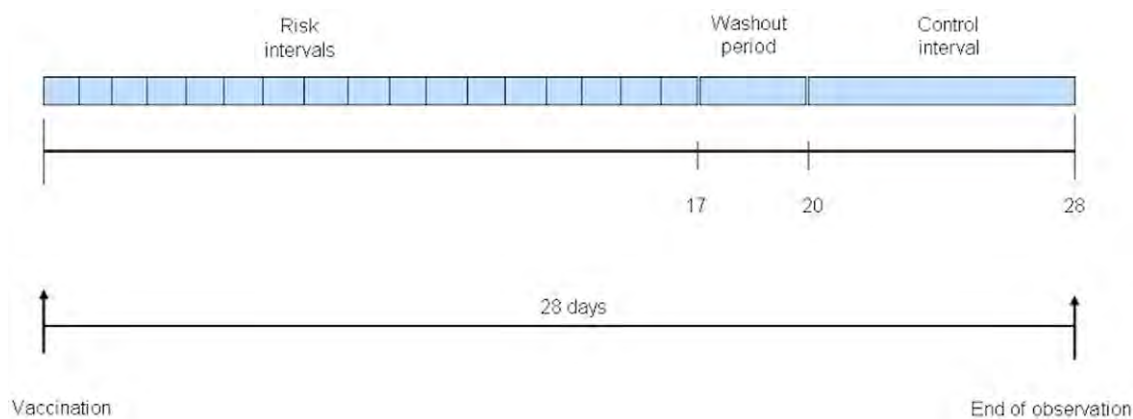


Figure 1. Illustration of the self-controlled case series design. The observation period for each patient begins with pediatric vaccination date (leftmost upward arrow) and continues for a total of 28 days. In the primary analyses, each day post vaccination is considered a *risk interval*, and consecutive days with a statistically significant elevation in relative incidence were pooled to create a combined risk interval. Days 20–28 comprise the *control interval*. The intervening days represent the wash-out period.
doi:10.1371/journal.pone.0027897.g001

vaccinations on the combined endpoint of emergency room visits and hospital admissions in selected periods post-vaccination.

Methods

Design

The overall goal of this study was to determine the risk of serious adverse events in all children vaccinated in Ontario at 12

and 18 months of age with recommended pediatric vaccines. This was measured by comparing the risk of either presentation to emergency room (ER), or hospital admission in consecutive one day periods after the date of vaccination compared to a later control period. This analysis was conducted on all children born between April 1st 2006 and March 31st 2009. Our primary analysis of the composite risk of ER visits and hospitalizations was conducted using the *self-controlled case-series design*, described by

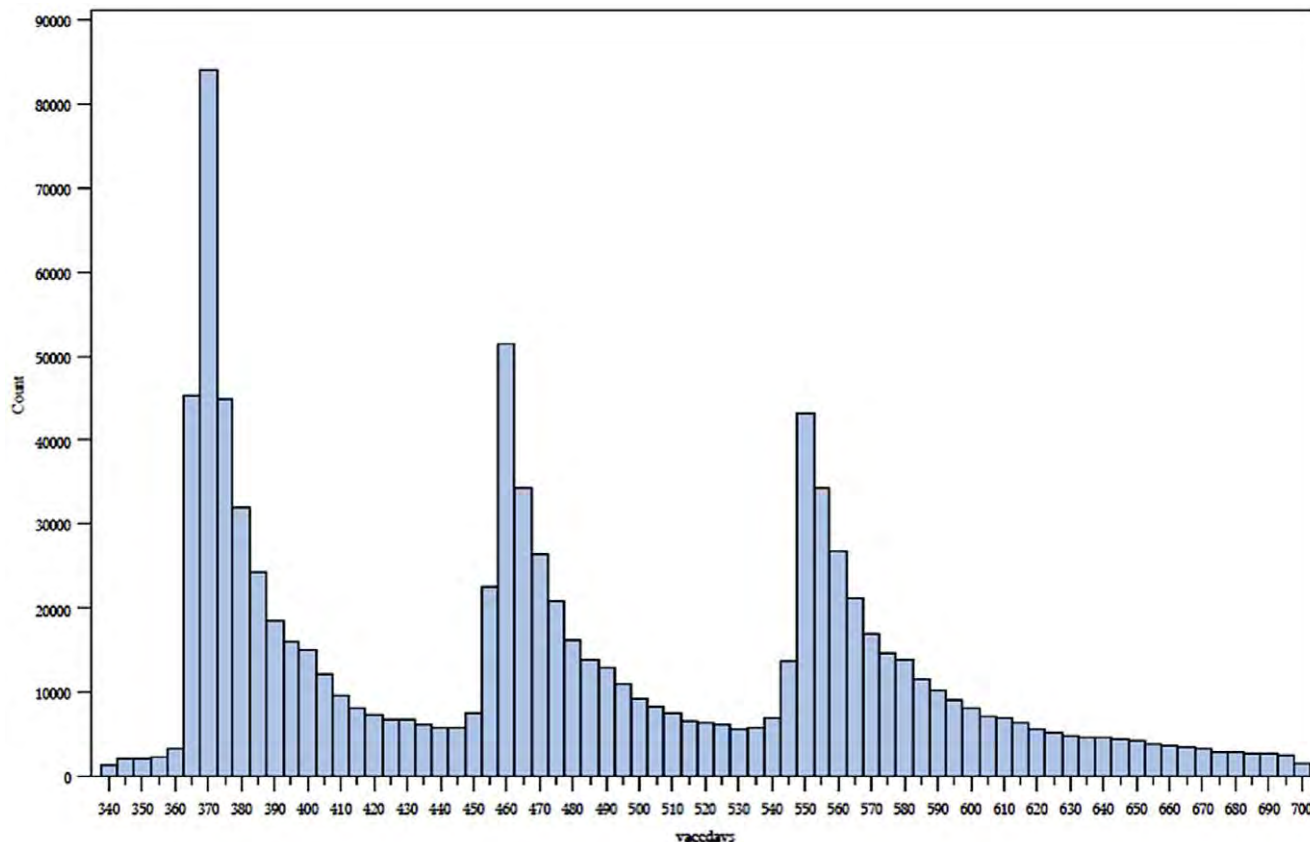


Figure 2. Vaccination events by days since birth from days 340 to 700. Count=number of individuals vaccinated on a given day. Days=number of days after date of birth.
doi:10.1371/journal.pone.0027897.g002

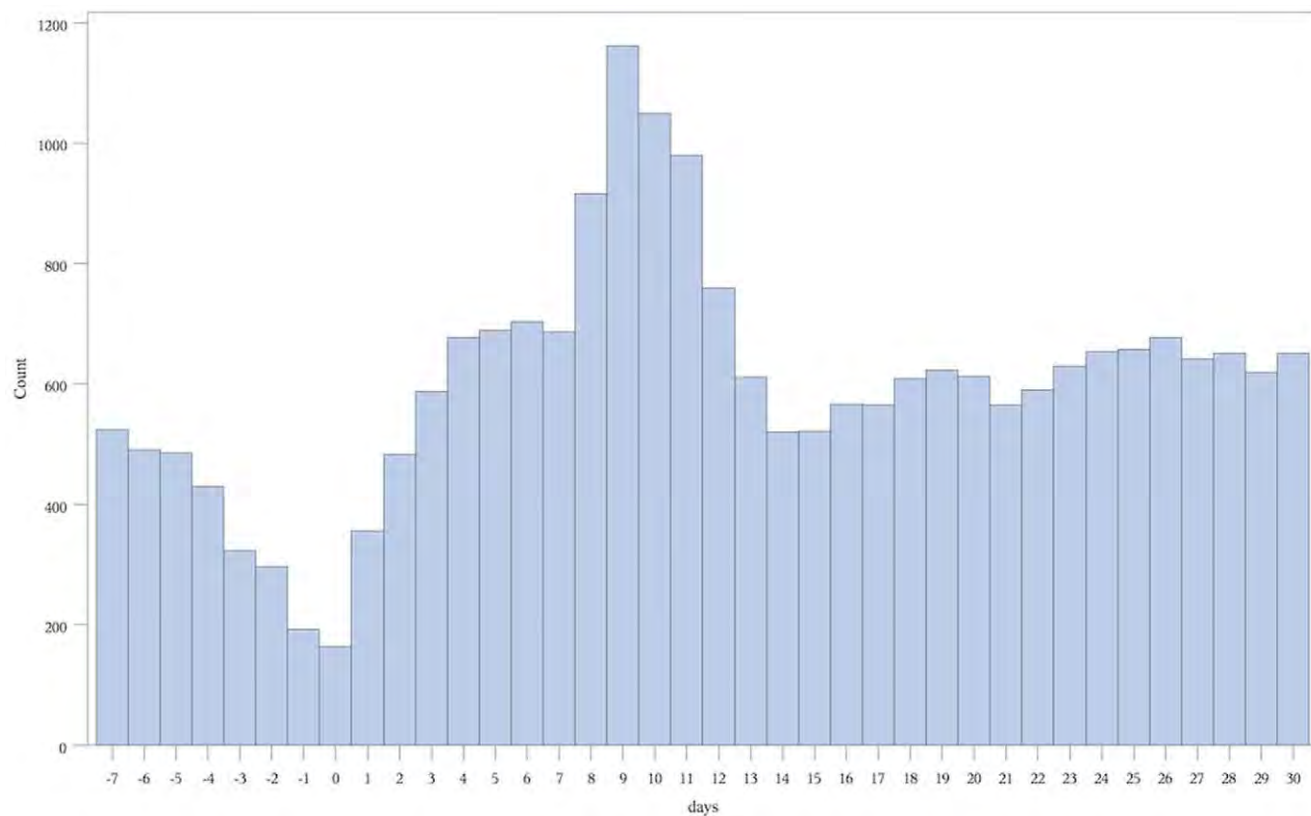


Figure 3. Number of combined endpoints versus days before/after 12 month vaccination. Count = number of combined endpoints of emergency room visit or hospitalization. Days = number of days before or after vaccination, day 0 being the day of vaccination.
doi:10.1371/journal.pone.0027897.g003

Farrington and associates [7,8]. We analyzed events following the 12 and 18 month vaccinations separately.

Data

Our study cohort included all children in the Newborn Screening Ontario data set between April 1st 2006 and March 31st 2009. This database captures over 99% of Ontario births. Our exposure of interest, pediatric vaccination, was identified using the Ontario Health Insurance Plan (OHIP) database. We used codes for general vaccination, as, except for influenza, vaccine-specific codes are not available. To identify the 12 and 18 month vaccinations separately we identified vaccination occurring on exactly the respective due dates as well as vaccinations occurring up to 60 days after the respective date. To allow adequate follow-up after the 12 month vaccination, only vaccinated children born on or before December 31st 2008 could be included in the analysis (N = 271,495 children). Likewise, only vaccinated children born on or before June 30th 2008 could be included in the analysis of adverse events after the 18 month vaccination (N = 184,312 children). Only subjects with both vaccinations and events in the observation period contribute to the conditional self-controlled case series analysis, therefore infants with no ER visits or hospitalizations in close proximity to the vaccination were not included. If infants had more than one vaccination in the database during the two month target period the first vaccination was used as the index vaccination. If another vaccination occurred within the observation period (0 to 28 days after the index vaccination), or the infant died, then this individual was excluded from analysis (see Appendix S1).

The Canadian Institute for Health Information's (CIHI) Discharge Abstract Database (DAD) captures all hospital admissions, including children in both tertiary and community hospitals, and was used to ascertain hospital admission. CIHI's National Ambulatory Care Registration System (NACRS) was used to ascertain ER visits, the Canadian Triage and Acuity Score (CTAS) rating and the diagnosis made by the most responsible physician for the visit. The Registered Persons Database was used to ascertain cases of death. These datasets are housed at the Institute for Clinical Evaluative Sciences (ICES), and linkage between datasets was achieved using encrypted health card numbers as unique identifiers. The study was performed within ICES' status as a Prescribed Entity in Ontario's privacy legislation and Research Ethics Board approval was received at OHRI and ICES (Sunnybrook).

Analysis

We graphed the number of combined endpoint events in the days before and after vaccination. In the self-controlled case series model, the date of vaccination serves as the index date for exposure for each patient. Previous studies have identified that children are at increased risk for systemic reactions at different times from 5–14 days after vaccination [5,6,9,10]. Because *a priori* we did not know with certainty the time period following vaccination for which there would be an increased risk of our combined endpoint, we modified the standard self-controlled case series approach by looking for an elevation in risk during each post-vaccination day up to day 17 (Figure 1). We then classified days 20–28 as unexposed, establishing a washout period in

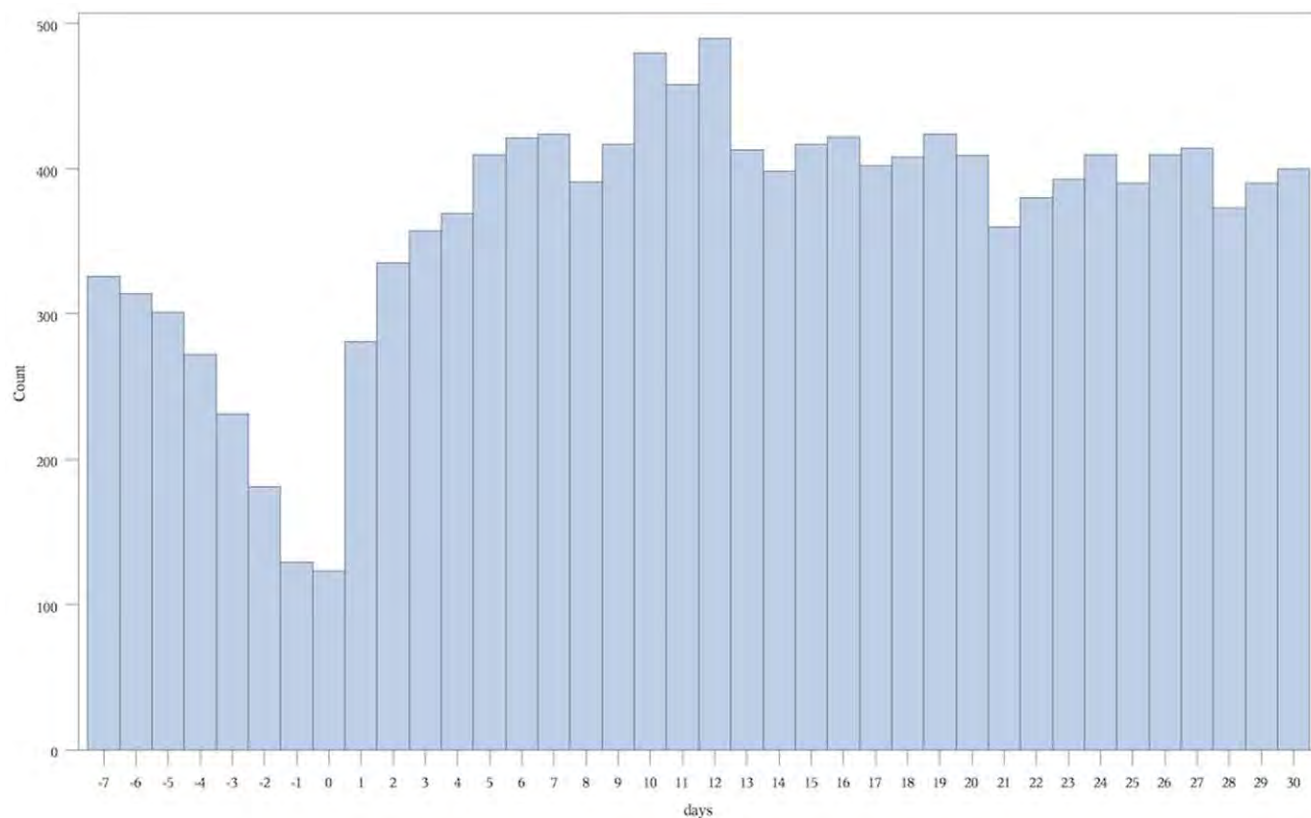


Figure 4. Number of combined endpoints versus days before/after 18 month vaccination. Count = number of combined endpoints of emergency room visit or hospitalization. Days = number of days before or after vaccination, day 0 being the day of vaccination. doi:10.1371/journal.pone.0027897.g004

between the exposed and unexposed periods (Figure 1). When multiple events occurred to a given individual, the first occurrence of the composite outcome in the post-vaccination period was used (eg., someone attending the ER who was then admitted would have one event counted in that period). The relative incidence rate of the composite endpoint during the exposed period compared with the unexposed period was analyzed using a fixed effects Poisson regression model. This model included a term for exposure period and a term for patient, thereby allowing each individual to serve as his or her own control and accounting for intra-individual correlation. An offset term was also included to account for the differing durations of the exposed and unexposed periods. Deaths after the 12 and 18 month vaccinations were explored in a separate analysis due to the fact that a subject dying effectively truncates their follow-up potentially biasing the results of the SCCS analysis. As noted above, children who died during the follow-up period were excluded from the SCCS analysis of ER visits and hospitalizations.

To define the at-risk period we combined consecutive days with statistically significant elevations in relative incidence. We considered statistical significance to be a p-value less than or equal to 0.001 based on a Bonferroni correction to account for multiple testing (38 separate tests) [11]. We conducted separate analyses for the 12 and 18 month vaccinations. We also conducted secondary analyses to determine the association between vaccination and ER visits, hospital admissions, and deaths separately. All p values were 2 sided, and analyses were conducted using SAS version 9.2 (SAS Institute, Cary, NC).

In order to assess the types of cases captured by our endpoints we conducted a post-hoc analysis where we compiled the reasons for presentation to the ER as determined by the most responsible physician for the risk period for the 12 month vaccination. This was compared to the prevalence of the same diagnoses in the control period. We examined a tracer condition, ear/face nose injury, for which we do not expect a difference in rates. We also identified the CTAS ratings for presentations during the affected period and compared them to those during the control period using the Wilcoxon Rank-Sum test. CTAS ratings range from 1 to 5 with 1 representing a severe condition requiring resuscitation and 5 representing a less severe condition requiring non-urgent care [12]. In another post-hoc analysis we graphically examined the pattern of events following 12 and 18 month vaccination in the years 2002–2005 when the MMR vaccine was still given at 12 months, however, the booster was given at five years and not eighteen months.

Results

In total, we examined 455,807 separate vaccination events in these 413,957 children that occurred at 12 and 18 months plus 60 days (Figure 2). We present the number of endpoint events versus days pre and post vaccination graphically for each of the vaccine periods (Figures 3 and 4).

12 month analysis

271,495 children received vaccinations between 365 and 425 days of age. Consecutive statistically significant elevations in combined endpoints began on day 4 and continued to day 12. A

Table 1. Relative incidence of combined endpoint (hospital admission or emergency room visit) following 12 month vaccination.

Risk interval*	Endpoints during risk interval (n)	Relative Incidence (95% CI)	P value
Day 4	621	1.15 (1.06–1.25)	0.0008
Day 5	641	1.19 (1.10–1.29)	<0.0001
Day 6	647	1.20 (1.11–1.31)	<0.0001
Day 7	644	1.20 (1.10–1.30)	<0.0001
Day 8	870	1.62 (1.50–1.74)	<0.0001
Day 9	1096	2.04 (1.91–2.17)	<0.0001
Day 10	991	1.84 (1.72–1.97)	<0.0001
Day 11	923	1.72 (1.60–1.84))	<0.0001
Day 12	713	1.32 (1.22–1.43)	<0.0001
Days 4 to 12** (Combined risk interval)	6462	1.33(1.29–1.38)	<0.0001
Days 20–28 (Control Interval)	4845	NA	NA

*Risk and control intervals expressed as days following vaccination.

**Total number of endpoints in the combined risk interval are less than the cumulative individual day event total because some children may have experienced events in multiple days and only the first event is counted.

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total of 6462 children experienced at least one of the combined endpoints during the combined 9 day at risk period compared to 4845 during the 9 day control period. The relative incidence of the combined endpoint was 1.33 (1.29–1.38) (Table 1). The highest relative incidence during the at-risk period occurred between days 8 and 11 peaking at 2.04 (1.91–2.17) on day 9. Overall, an excess of 595 children experienced at least one of the combined endpoints during the risk interval per 100,000 vaccinated, or one additional child experiencing at least one endpoint during the risk interval for every 168 children who received their 12 month vaccinations (Table 2). Examining the historical graph of the events post 12 month vaccination in the years 2002–2005 demonstrated a similar peak in events (Figure 5).

The primary reason for the elevation in the combined endpoint was an increase in ER visits (relative incidence 1.34(1.29–1.39)). There were an excess of 598 children experiencing 1 or more ER visits during the risk interval per 100,000 vaccinations or 1 additional child for every 168 children vaccinated. There was no increase in hospital admissions (relative incidence 1.08 (0.93–1.25)). There were five or fewer deaths (Table 3). The average CTAS score for ER visits during the risk period was 3.27 compared to 3.26 for the control period. ($p = 0.74$), suggesting no differences in severity of presentation between ER visits in the risk and control periods. There was an increase in presentation for multiple conditions during the risk period compared to the control period. The largest relative risk was associated with febrile seizures (relative incidence = 2.34, fever (RI = 2.31) and viral exanthem (RI = 2.23). We calculated that there were approximately 20 additional febrile seizures during the risk interval for every 100 000 children vaccinated. There was no increase in our tracer condition (ear/face/nose injury).

18 month analysis

184,312 children received vaccinations between 545 and 605 days of age. Consecutive statistically significant elevations in combined endpoints began on day 10 and continued to day 12. A total of 1275 children experienced at least one event included in the combined endpoint during the combined three day at risk period compared to 3065 during the nine day control period. The relative incidence of the combined endpoint was 1.25 (1.17–1.33) (Table 4). The highest relative incidence during the at-risk period was 1.34 (1.21–1.47) which occurred on day 12. Overall, an additional 137 children experienced at least one combined endpoint during the three day risk period per 100,000 vaccinated, or one additional child experiencing at least one excess event for every 730 children vaccinated (Table 3). Examining the historical graph of the events post 18 month vaccination in the years 2002–2005, when the booster dose of the MMR vaccine was not given, demonstrated no similar peak in events (Figure 5).

The primary reason for the elevation in the combined endpoint was an increase in ER visits (relative incidence 1.25(1.18–1.34)). There were an excess of 139 children experiencing one or more ER visits during the risk interval or one excess visit for every 719 children vaccinated. There was not a significant increase in hospital admissions (relative incidence 1.23(0.94–1.59)) (Table 4). No deaths occurred in the risk or control periods.

Discussion

Our analysis demonstrated that the 12 and 18 month vaccinations are not associated with an increase in adverse events immediately following vaccination. Instead it showed a reduced risk in this period, which is likely a result of the previously

Table 2. Increased risk of combined endpoints from vaccination.

Vaccination	Additional children experiencing at least one event (per 100,000 vaccinations)	Number vaccinated	Number vaccinated per excess event
12 months	595	271,495	168
18 months	137	184,312	730

doi:10.1371/journal.pone.0027897.t002

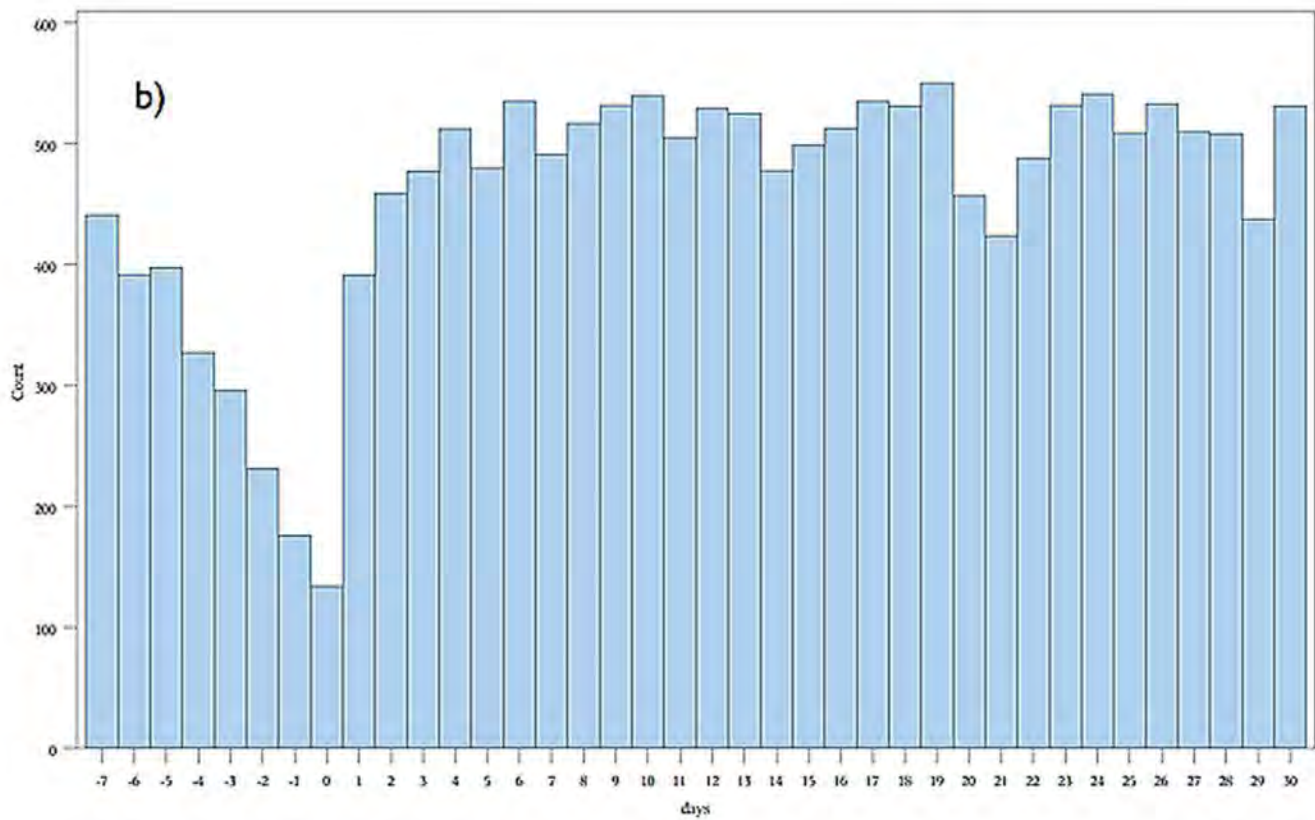
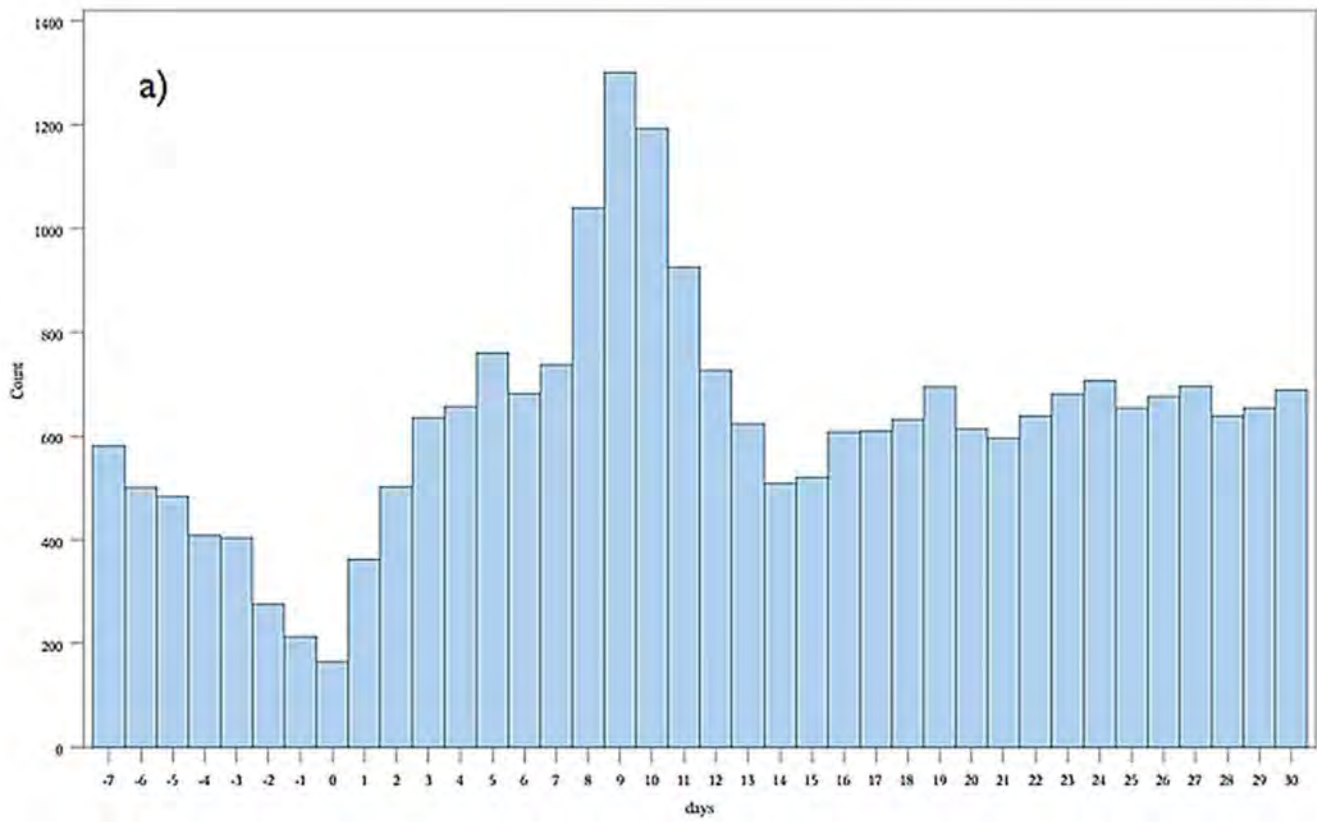


Figure 5. Historical analysis of combined endpoints versus days following 12 and 18 month vaccination: April 2002–March 2005. a) Before/after 12 month vaccination. b) Before/after 18 month vaccination. **Count**= number of combined endpoints of emergency room visit or hospitalization. **Days**= number of days before or after vaccination, day 0 being the day of vaccination. doi:10.1371/journal.pone.0027897.g005

documented healthy vaccinee effect [9,13,14]. We identified an increase in events occurring between 4 and 12 days post-vaccination for the 12 month and, to a lesser extent and for a shorter time period for the 18 month vaccines. The majority of these events represented ER visits and at their peak, on day 9 following the 12 month vaccine, were approximately twice the baseline rate. Although there was an increase in hospital admission in each period, none of these increases were statistically significant. Overall the increase in event rate following the 12 month vaccines accounted for approximately 598 extra children experiencing one or more ER visits during the risk interval per 100,000 vaccinations. The average acuity of patients presenting to the emergency room was similar to that in the control period. The conditions for which there were the largest increase in risk for presentation to the emergency room during the risk interval compared to the control interval following the 12 month vaccine were febrile convulsions, fever and viral exanthema, consistent with the known adverse event profile of MMR and varicella vaccines. There were 20 additional febrile seizures for every 100,000 children vaccinated at 12 months.

The development of an inflammatory response approximately one week after vaccination is recognized in the literature. For example, the Centres for Disease Control and Prevention list days 7 to 12 post vaccination as the highest risk period for developing fever and possibly a rash [15]. This closely coincides with our observation of the time period during which emergency room visits peaked. A previous twin study also identified the development of systemic symptoms between days 6 and 14 and peaking on day 10 [9]. A study of febrile seizures following MMR vaccination identified the highest at risk period to be 8 to 14 days following vaccination and a relative risk of 2.83 and other studies have made similar observations [5,6,16]. These are consistent with our findings. While it is known that vaccines can produce these adverse events, our study demonstrated the population wide impact of this effect and that these events are resulting in an increase in health services utilization. The estimated 595 additional children experiencing at least one event for every 100 000 vaccinated translates into approximately one child experiencing at least one event per 168 children vaccinated. The explanation for this effect is likely the controlled replication of the virus creating a mild form of the illness the vaccine is designed to prevent. The top diagnoses for the presentations to the emergency room during the 12 month risk interval would all be consistent with a mild viral illness.

The reduced effect at 18 months is likely due to this vaccination in most instances being a second exposure to the antigen to which the vast majority of children would have developed adequate

immunity. Residual events during this period may represent the small percentage of children who did not immunologically respond to the first dose of the vaccine.

Our study has several strengths. The use of the self-controlled case series design allows for individuals to serve as their own controls implicitly controlling for all fixed covariates [8,17]. Seasonal confounding is unlikely to have influenced our findings since the 12 and 18th month vaccines are provided throughout the year. The potential for confounding due to co-existent exposures at 12 and 18 months exists, however, if such an exposure were to be significant we would have expected to observe an effect at 18 months in our historical analysis. Our study included nearly all children born in Ontario during the study period which strengthens the generalizability of these findings. The combination of the self-controlled case series design and our sample size increased the power of our study to identify small effects. While our study cannot establish causality it has many features that support a causal relationship between vaccination and delayed adverse events. These include the consistency with other studies and a compelling biological model which explains the diagnoses in the affected children and the reduction in effect with the 18 month vaccinations. Furthermore, our historical analysis demonstrates that the effect seen at 18 months after MMR vaccination in 2006–2009 is not present in 2002–2005, when the MMR vaccine was given only at 12 months and not at 18 months. The effect is still clearly visible after the 12 month vaccination in the 2002–2005 data.

There are important limitations of this study. The first is that, as mentioned, the healthy vaccinee effect may have masked an association in the immediate post-vaccination period. Second, we cannot know whether a specific vaccine was associated with the adverse events as multiple vaccines are typically administered at each visit. However, we have previously demonstrated the safety of the pentavalent vaccine which is given with the 18 month MMR vaccine [18]. It is possible that the effects seen at 12 month are in part due to the potential co-administration of the meningococcal C vaccine, however, this is not a live vaccine and should create inflammation in the immediate post-vaccination period as opposed to one week later. Third, the codes we used for identifying the reasons for presentation to the emergency room have not been validated. However, we would expect that the diagnoses of febrile convulsion to have a low misclassification error and has previously been validated as a useful ER code in a separate dataset [19]. We also did not look for increases in visits to physician offices that did not result in presentation to the emergency room or admission and cannot comment on the impact of immunization on that outcome.

Table 3. Relative incidences of individual endpoints (emergency room visit, hospital admission, death) during highest risk interval compared to control period.

Outcome	12 months	Events (risk/control)	18 months	Events (risk/control)
Emergency visits	1.34 (1.29–1.39)	6395/4772	1.25 (1.18–1.34)	1264/3024
Admissions	1.08 (0.93–1.25)	356/330	1.23 (0.94–1.59)	78/191
Deaths	-	< = 5/< = 5	-	0/0

doi:10.1371/journal.pone.0027897.t003

Table 4. Relative incidence of combined endpoint (hospital admission or emergency room visit) following 18 month vaccination.

Risk interval*	Endpoints during risk interval (n)	Relative Incidence (95% CI)	P value
Days 10	447	1.31 (1.19–1.45)	<0.0001
Days 11	428	1.26 (1.14–1.39)	<0.0001
Days 12	455	1.34 (1.21–1.47)	<0.0001
Days 10 to 12 (Combined risk interval)	1275	1.25 (1.17,1.33)	<0.0001
Days 20 to 28 (Control Interval)	3065	NA	NA

*Risk and control intervals expressed as days following vaccination.
doi:10.1371/journal.pone.0027897.t004

Our findings have important implications for those providing care to children. The immediate risk of a serious adverse event following immunization is low with both the vaccination visits that contain the MMR and varicella vaccines. However, the 12 month vaccines which typically contain the first dose of the MMR vaccine is associated with an increased risk of an emergency room visit approximately 4 to 12 days after immunization, peaking between days 8 and 11. This increase in rate of a child experiencing at least one event for every 158 vaccinated individuals is associated with a similar acuity as the control period. If the presentation to the emergency room was due to parental anxiety we would have expected to see a reduction in acuity during the risk period. The findings also suggest that the reactions are not severe since acuity was not higher than the control period and furthermore, there were few hospital admissions. Additional reassurance can be derived from previous studies that identified no long-term consequences related to vaccine associated febrile seizures [5,6]. The increase in ER visits we observed could be a result of insufficient information being provided to parents who may not expect their child to develop a reaction a week after vaccination. In particular, the likelihood of this risk may be underestimated by physicians. Our study also reinforces the reduced risk of events following the second dose of MMR vaccine.

Given the effectiveness of the MMR vaccine in eliminating both measles and rubella, and the highly infectious nature of these diseases, high vaccination coverage is essential. The diseases that the vaccines are preventing are not benign and vaccination can eliminate many of the serious sequelae of these infections [20]. Complications from measles include otitis media (7–9% of cases), pneumonia (1–6% of cases), encephalitis (1 per 1,000–2,000 cases), subacute sclerosing panencephalitis (1 per 100,000 cases), and death (1 per 3000 cases) [3,21]. Further studies attempting to predict which children develop post-vaccination reactions, as well as determining the effectiveness of prophylactic treatment with antipyretics prior to the high risk period for symptom development are warranted.

Supporting Information

Appendix S1 Figure A1: Flowchart Describing SCCS Study Cohort.
(TIF)

Author Contributions

Conceived and designed the experiments: KW SH DM JK SD NC. Performed the experiments: SH. Analyzed the data: KW SH CV DM JK. Wrote the paper: KW SH JK MP SD NC BP PC.

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Exhibit NN

42 USCS § 300aa-27

Current through PL 116-8, approved 3/8/19

United States Code Service - Titles 1 through 54 > TITLE 42. THE PUBLIC HEALTH AND WELFARE > CHAPTER 6A. THE PUBLIC HEALTH SERVICE > VACCINES > NATIONAL VACCINE INJURY COMPENSATION PROGRAM > ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

§ 300aa-27. Mandate for safer childhood vaccines

(a) General rule. In the administration of this subtitle [[42 USCS §§ 300aa-10](#) et seq.] and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall--

- (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part [effective Dec. 22, 1987] and promote the refinement of such vaccines, and
- (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force.

- (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
- (2) The Director of the National Institutes of Health shall serve as chairman of the task force.
- (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report. Within 2 years after the effective date of this part [effective Dec. 22, 1987], and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

History

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part C, § 2127, as added Nov. 14, 1986, [P.L. 99-660](#), Title III, Part A, § 311(a), [100 Stat. 3777](#); Dec. 22, 1987, [P.L. 100-203](#), Title IV, Subtitle D, § 4302(b)(1), [101 Stat. 1330-221](#); Dec. 19, 1989, [P.L. 101-239](#), Title VI, Subtitle D, § 6601(q), [103 Stat. 2292](#).)

UNITED STATES CODE SERVICE

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Exhibit 00



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
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Via email: aaron@sirillp.com

June 22, 2018

Aaron Siri, Esq.
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Re: FOI Case No. 47575, 47756, 47782, 47783, 47881

Dear Mr. Siri:

This is the final response to your Freedom of Information Act (FOIA) requests dated February 15, April 10, April 16, and May 10, 2018, addressed to the FOIA Office, National Institutes of Health, (NIH) and received in this office on those same days. You requested: A copy of all materials associated with the meetings held by the Task Force on Safe Childhood Vaccines, (NIH FOIA Case Number 47575), a copy of the charter for the Task Force for Safer Childhood Vaccines (NIH FOIA Case Number 47756), all agendas, minutes, and transcripts of meetings held by the Task Force on Safer Childhood Vaccines, as well as records sufficient to reflect the dates of these meetings, any and all recommendations made by the Task Force for Safer Childhood Vaccines, and any and all resolutions voted upon by the Task Force on Safer Childhood Vaccines established pursuant to 42 U.S.C. § 300aa-27(b) (NIH FOIA Case Number 47782, 47783, and 47881). All of the aforementioned requests stipulated the same search dates from January 1, 2009 to present.

We queried the files of the NIH Office of the Director, Executive Secretariat, as well as the National Institute of Allergies and Infectious Diseases (NIAID) and no records responsive to your requests, 47575, 47782, 47783, and 47881 were found. **Please be advised that the Task Force for Safer Childhood Vaccines was disbanded in 1998.**

We have found one record in connection with your request, 47756: The only record that we could find approaching that description is the attached letter establishing the Task Force in 1990. While this date falls out of the timeframe of your request, January 1, 2009 to present, we include this record with this response letter as a courtesy.

Please note that, we are in the process of gathering records responsive to your most recent request, 48013, regarding, "A copy of any and all recommendations made by the Task Force on Safer Childhood Vaccines," from December 22, 1987 to present. We will review those records once that case is next in the queue for review. It is still behind several other cases as of the date of this letter, and all cases will be processed on a first-in first-out basis as mandated by the FOIA.

Page 2 – Mr. Siri (47575, 47756, 47782, 47783, 47881)

If you are not satisfied with the processing and handling of this request you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

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In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response please call 301-496-5633.

Sincerely,



Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosed: 1 page, PDF

Exhibit PP

Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

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Abstract

Vaccinations have prevented millions of infectious illnesses, hospitalizations and deaths among U.S. children, yet the long-term health outcomes of the vaccination schedule remain uncertain. Studies have been recommended by the U.S. Institute of Medicine to address this question. This study aimed 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, and 2) to determine whether an association found between vaccination and neurodevelopmental disorders (NDD), if any, remained significant after adjustment for other measured factors. A cross-sectional study of mothers of children educated at home was carried out in collaboration with homeschool organizations in four U.S. states: Florida, Louisiana, Mississippi and Oregon. Mothers were asked to complete an anonymous online questionnaire on their 6- to 12-year-old biological children with respect to pregnancy-related factors, birth history, vaccinations, physician-diagnosed illnesses, medications used, and health services. NDD, a derived diagnostic measure, was defined as having one or more of the following three closely-related diagnoses: a learning disability, Attention Deficient Hyperactivity Disorder, and Autism Spectrum Disorder. A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated. The vaccinated were less likely than the unvaccinated to have been diagnosed with chickenpox and pertussis, but more likely to have been diagnosed with pneumonia, otitis media, allergies and NDD. After adjustment, vaccination, male gender, and preterm birth remained significantly associated with NDD. However, in a final adjusted model with interaction, vaccination but not preterm birth remained associated with NDD, while the interaction of preterm birth and vaccination was associated with a 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5). In conclusion, vaccinated homeschool children were found to have a higher rate of allergies and NDD than unvaccinated homeschool children. While vaccination remained significantly associated with NDD after controlling for other factors, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD. Further research involving larger, independent samples and stronger research designs is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children's health.

Abbreviations: ADHD: Attention Deficit Hyperactivity Disorder; ASD: Autism Spectrum Disorder; AOM: Acute Otitis Media; CDC: Centers for Disease Control and Prevention; CI: Confidence Interval; NDD: Neurodevelopmental Disorders; NHERI: National Home Education Research Institute; OR: Odds Ratio; PCV-7: Pneumococcal Conjugate Vaccine-7; VAERS: Vaccine Adverse Events Reporting System.

Introduction

Vaccines are among the greatest achievements of biomedical science and one of the most effective public health interventions of the 20th century [1]. Among U.S. children born between 1995 and 2013, vaccination is estimated to have prevented 322 million illnesses, 21 million hospitalizations and 732,000 premature deaths, with overall cost savings of \$1.38 trillion [2]. About 95% of U.S. children of kindergarten age receive all of the recommended vaccines as a requirement for school and daycare attendance [3,4], aimed at preventing the occurrence and spread of targeted infectious diseases [5]. Advances in biotechnology are contributing to the development of new vaccines for widespread use [6].

Under the currently recommended pediatric vaccination schedule [7], U.S. children receive up to 48 doses of vaccines for 14 diseases from birth to age six years, a figure that has steadily increased since the 1950s, most notably since the Vaccines for Children program was created in 1994. The Vaccines for Children program began with vaccines targeting nine diseases: diphtheria, tetanus, pertussis, polio,

Haemophilus influenzae type b disease, hepatitis B, measles, mumps, and rubella. Between 1995 and 2013, new vaccines against five other diseases were added for children age 6 and under: varicella, hepatitis A, pneumococcal disease, influenza, and rotavirus vaccine.

Although short-term immunologic and safety testing is performed on vaccines prior to their approval by the U.S. Food and Drug Administration, the long-term effects of individual vaccines and of the vaccination program itself remain unknown [8]. Vaccines are acknowledged to carry risks of severe acute and chronic adverse effects, such as neurological complications and even death [9], but such risks are considered so rare that the vaccination program is believed to be safe and effective for virtually all children [10].

There are very few randomized trials on any existing vaccine recommended for children in terms of morbidity and mortality, in

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Key words: acute diseases, chronic diseases, epidemiology, evaluation, health policy, immunization, neurodevelopmental disorders, vaccination

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Mawson AR (2017) Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

part because of ethical concerns involving withholding vaccines from children assigned to a control group. One exception, the high-titer measles vaccine, was withdrawn after several randomized trials in west Africa showed that it interacted with the diphtheria-tetanus-pertussis vaccine, resulting in a significant 33% increase in child mortality [11]. Evidence of safety from observational studies includes a limited number of vaccines, e.g., the measles, mumps and rubella vaccine, and hepatitis B vaccine, but none on the childhood vaccination program itself. Knowledge is limited even for vaccines with a long record of safety and protection against contagious diseases [12]. The safe levels and long-term effects of vaccine ingredients such as adjuvants and preservatives are also unknown [13]. Other concerns include the safety and cost-effectiveness of newer vaccines against diseases that are potentially lethal for individuals but have a lesser impact on population health, such as the group B meningococcus vaccine [14].

Knowledge of adverse events following vaccinations is largely based on voluntary reports to the Vaccine Adverse Events Reporting System (VAERS) by physicians and parents. However, the rate of reporting of serious vaccine injuries is estimated to be <1% [15]. These considerations led the former Institute of Medicine (now the National Academy of Medicine) in 2005 to recommend the development of a five-year plan for vaccine safety research by the Centers for Disease Control and Prevention (CDC) [16,17]. In its 2011 and 2013 reviews of the adverse effects of vaccines, the Institute of Medicine concluded that few health problems are caused by or associated with vaccines, and found no evidence that the vaccination schedule was unsafe [18,19]. Another systematic review, commissioned by the US Agency for Healthcare Research and Quality to identify gaps in evidence on the safety of the childhood vaccination program, concluded that severe adverse events following vaccinations are extremely rare [20]. The Institute of Medicine, however, noted that studies were needed: to compare the health outcomes of vaccinated and unvaccinated children; to examine the long-term cumulative effects of vaccines; the timing of vaccination in relation to the age and condition of the child; the total load or number of vaccines given at one time; the effect of other vaccine ingredients in relation to health outcomes; and the mechanisms of vaccine-associated injury [19].

A complicating factor in evaluating the vaccination program is that vaccines against infectious diseases have complex nonspecific effects on morbidity and mortality that extend beyond prevention of the targeted disease. The existence of such effects poses a challenge to the assumption that individual vaccines affect the immune system independently of each other and have no physiological effect other than protection against the targeted pathogen [21]. The nonspecific effects of some vaccines appear to be beneficial, while in others they appear to increase morbidity and mortality [22,23]. For instance, both the measles and Bacillus Calmette–Guérin vaccine reportedly reduce overall morbidity and mortality [24], whereas the diphtheria-tetanus-pertussis [25] and hepatitis B vaccines [26] have the opposite effect. The mechanisms responsible for these nonspecific effects are unknown but may involve *inter alia*: interactions between vaccines and their ingredients, e.g., whether the vaccines are live or inactivated; the most recently administered vaccine; micronutrient supplements such as vitamin A; the sequence in which vaccines are given; and their possible combined and cumulative effects [21].

A major current controversy is the question of whether vaccination plays a role in neurodevelopmental disorders (NDDs), which broadly include learning disabilities, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD). The controversy has

been fueled by the fact that the U.S. is experiencing what has been described as a “silent pandemic” of mostly subclinical developmental neurotoxicity, in which about 15% of children suffer from a learning disability, sensory deficits, and developmental delays [27,28]. In 1996 the estimated prevalence of ASD was 0.42%. By 2010 it had risen to 1.47% (1 in 68), with 1 in 42 boys and 1 in 189 girls affected [29]. More recently, based on a CDC survey of parents in 2011–2014, 2.24% of children (1 in 45) were estimated to have ASD. Rates of other developmental disabilities, however, such as intellectual disability, cerebral palsy, hearing loss, and vision impairments, have declined or remained unchanged [30]. Prevalence rates of Attention Deficit Hyperactivity Disorder (ADHD) have also risen markedly in recent decades [31]. Earlier increases in the prevalence of learning disability have been followed by declining rates in most states, possibly due to changes in diagnostic criteria [32].

It is believed that much of the increase in NDD diagnoses in recent decades has been due to growing awareness of autism and more sensitive screening tools, and hence to greater numbers of children with milder symptoms of autism. But these factors do not account for all of the increase [33]. The geographically widespread increase in ASD and ADHD suggests a role for an environmental factor to which virtually all children are exposed. Agricultural chemicals are a current focus of research [34-37].

A possible contributory role for vaccines in the rise in NDD diagnoses remains unknown because data on the health outcomes of vaccinated and unvaccinated children are lacking. The need for such studies is suggested by the fact that the Vaccine Injury Compensation Program has paid \$3.2 billion in compensation for vaccine injury since its creation in 1986 [38]. A study of claims compensated by the Vaccine Injury Compensation Program for vaccine-induced encephalopathy and seizure disorder found 83 claims that were acknowledged as being due to brain damage. In all cases it was noted by the Court of Federal Claims, or indicated in settlement agreements, that the children had autism or ASD [39]. On the other hand, numerous epidemiological studies have found no association between receipt of selected vaccines (in particular the combined measles, mumps, and rubella vaccine) and autism [10,40-45], and there is no accepted mechanism by which vaccines could induce autism [46].

A major challenge in comparing vaccinated and unvaccinated children has been to identify an accessible pool of unvaccinated children, since the vast majority of children in the U.S. are vaccinated. Children educated at home (“homeschool children”) are suitable for such studies as a higher proportion are unvaccinated compared to public school children [47]. Homeschool families have an approximately equal median income to that of married-couple families nationwide, somewhat more years of formal education, and a higher average family size (just over three children) compared to the national average of just over two children [48-50]. Homeschooling families are slightly overrepresented in the south, about 23% are nonwhite, and the age distribution of homeschool children in grades K-12 is similar to that of children nationwide [51]. About 3% of the school-age population was homeschooled in the 2011-2012 school year [52].

The aims of this study were 1) to compare vaccinated and unvaccinated children on a broad range of health outcomes, including acute and chronic conditions, medication and health service utilization, and 2) to determine whether an association found between vaccination and NDDs, if any, remained significant after adjustment for other measured factors.

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Methods

Study planning

To implement the study, a partnership was formed with the National Home Education Research Institute (NHERI), an organization that has been involved in educational research on homeschooling for many years and has strong and extensive contacts with the homeschool community throughout the country (www.nheri.org). The study protocol was approved by the Institutional Review Board of Jackson State University.

Study design

The study was designed as a cross-sectional survey of homeschooling mothers on their vaccinated and unvaccinated biological children ages 6 to 12. As contact information on homeschool families was unavailable, there was no defined population or sampling frame from which a randomized study could be carried out, and from which response rates could be determined. However, the object of our pilot study was not to obtain a representative sample of homeschool children but a convenience sample of unvaccinated children of sufficient size to test for significant differences in outcomes between the groups.

We proceeded by selecting 4 states (Florida, Louisiana, Mississippi, and Oregon) for the survey (Stage 1). NHERI compiled a list of statewide and local homeschool organizations, totaling 84 in Florida, 18 in Louisiana, 12 in Mississippi and 17 in Oregon. Initial contacts were made in June 2012. NHERI contacted the leaders of each statewide organization by email to request their support. A second email was then sent, explaining the study purpose and background, which the leaders were asked to forward to their members (Stage 2). A link was provided to an online questionnaire in which no personally identifying information was requested. With funding limited to 12 months, we sought to obtain as many responses as possible, contacting families only indirectly through homeschool organizations. Biological mothers of children ages 6-12 years were asked to serve as respondents in order to standardize data collection and to include data on pregnancy-related factors and birth history that might relate to the children's current health. The age-range of 6 to 12 years was selected because most recommended vaccinations would have been received by then.

Recruitment and informed consent

Homeschool leaders were asked to sign Memoranda of Agreement on behalf of their organizations and to provide the number of member families. Non-responders were sent a second notice but few provided the requested information. However, follow-up calls to the leaders suggested that all had contacted their members about the study. Both the letter to families and the survey questions were stated in a neutral way with respect to vaccines. Our letter to parents began:

"Dear Parent, This study concerns a major current health question: namely, whether vaccination is linked in any way to children's long-term health. Vaccination is one of the greatest discoveries in medicine, yet little is known about its long-term impact. The objective of this study is to evaluate the effects of vaccination by comparing vaccinated and unvaccinated children in terms of a number of major health outcomes..."

Respondents were asked to indicate their consent to participate, to provide their home state and zip code of residence, and to confirm that they had biological children 6 to 12 years of age. The communications company Qualtrics (<http://qualtrics.com>) hosted the survey website. The questionnaire included only closed-ended questions requiring yes or no responses, with the aim of improving both response and completion rates.

A number of homeschool mothers volunteered to assist NHERI promote the study to their wide circles of homeschool contacts. A number of nationwide organizations also agreed to promote the study in the designated states. The online survey remained open for three months in the summer of 2012. Financial incentives to complete the survey were neither available nor offered.

Definitions and measures

Vaccination status was classified as unvaccinated (i.e., no previous vaccinations), partially vaccinated (received some but not all recommended vaccinations) and fully vaccinated (received all recommended age-appropriate vaccines), as reported by mothers. These categories were developed on the premise that any long-term effects of vaccines would be more evident in fully-vaccinated than in partially-vaccinated children, and rare or absent in the unvaccinated. Mothers were asked to use their child's vaccination records to indicate the recommended vaccines and doses their child had received. Dates of vaccinations were not requested in order not to overburden respondents and to reduce the likelihood of inaccurate reporting; nor was information requested on adverse events related to vaccines, as this was not our purpose. We also did not ask about dates of diagnoses because chronic illnesses are often gradual in onset and made long after the appearance of symptoms. Since most vaccinations are given before age 6, vaccination would be expected to precede the recognition and diagnosis of most chronic conditions.

Mothers were asked to indicate on a list of more than 40 acute and chronic illnesses all those for which her child or children had received a diagnosis by a physician. Other questions included the use of health services and procedures, dental check-ups, "sick visits" to physicians, medications used, insertion of ventilation ear tubes, number of days in the hospital, the extent of physical activity (number of hours the child engaged in "vigorous" activities on a typical weekday), number of siblings, family structure (mother and father living in the home, divorced or separated), family income and/or highest level of education of mother or father, and social interaction with children outside the home (i.e., amount of time spent in play or other contact with children outside the household). Questions specifically for the mother included pregnancy-related conditions and birth history, use of medications during pregnancy, and exposure to an adverse environment (defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory). NDD, a derived diagnostic category, was defined as having one or more of the following three closely related and overlapping diagnoses: a learning disability, Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD) [53].

Statistical methods

Unadjusted bivariate analyses using chi-square tests were performed initially to test the null hypothesis of no association between vaccination status and health outcomes, i.e., physician-diagnosed acute and chronic illnesses, medications, and the use of health services. In most analyses, partially and fully vaccinated children were grouped together as the "vaccinated" group, with unvaccinated children as the control group. The second aim of the study was to determine whether any association found between vaccination and neurodevelopmental disorders remained significant after controlling for other measured factors. Descriptive statistics on all variables were computed to determine frequencies and percentages for categorical variables and means (\pm SD) for continuous variables. The strength of associations

Mawson AR (2017) Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children

between vaccination status and health outcomes were tested using odds ratios (OR) and 95% Confidence Intervals (CI). Odds ratios describe the strength of the association between two categorical variables measured simultaneously and are appropriate measures of that relationship in a cross-sectional study [54]. Unadjusted and adjusted logistic regression analyses were carried out using SAS (Version 9.3) to determine the factors associated with NDDs.

Results

Socio-Demographic characteristics of respondents

The information contained in 415 questionnaires provided data on 666 homeschool children. Table 1 shows the characteristics of the survey respondents. Mothers averaged about 40 years of age, were typically white, college graduates, with household incomes between \$50,000 to \$100,000, Christian, and married. The reasons for homeschooling for the majority of respondents (80-86%) were for a moral environment, better family relationships, or for more contact with their child or children.

The children as a group were similarly mostly white (88%), with a slight preponderance of females (52%), and averaged 9 years of age. With regard to vaccination status, 261 (39%) were unvaccinated, 208 (31%) were partially vaccinated, and 197 (30%) had received all of the recommended vaccinations. All statistical analyses are based on these numbers.

Acute illness

Vaccinated children (N=405), combining the partially and fully vaccinated, were significantly less likely than the unvaccinated to have had chickenpox (7.9% vs. 25.3%, $p < 0.001$; Odds Ratio = 0.26, 95% Confidence Interval: 0.2, 0.4) and whooping cough (pertussis) (2.5% vs. 8.4%, $p < 0.001$; OR 0.3, 95% CI: 0.1, 0.6), and less likely, but not significantly so, to have had rubella (0.3% vs. 1.9%, $p = 0.04$; OR 0.1, 95% CI: 0.01, 1.1). However, the vaccinated were significantly more likely than the unvaccinated to have been diagnosed with otitis media (19.8% vs. 5.8%, $p < 0.001$; OR 3.8, 95% CI: 2.1, 6.6) and pneumonia (6.4% vs. 1.2%, $p = 0.001$; OR 5.9, 95% CI: 1.8, 19.7). No significant differences were seen with regard to hepatitis A or B, high fever in the past 6 months, measles, mumps, meningitis (viral or bacterial), influenza, or rotavirus (Table 2).

Chronic illness

Vaccinated children were significantly more likely than the unvaccinated to have been diagnosed with the following: allergic rhinitis (10.4% vs. 0.4%, $p < 0.001$; OR 30.1, 95% CI: 4.1, 219.3), other allergies (22.2% vs. 6.9%, $p < 0.001$; OR 3.9, 95% CI: 2.3, 6.6), eczema/atopic dermatitis (9.5% vs. 3.6%, $p = 0.035$; OR 2.9, 95% CI: 1.4, 6.1), a learning disability (5.7% vs. 1.2%, $p = 0.003$; OR 5.2, 95% CI: 1.6, 17.4), ADHD (4.7% vs. 1.0%, $p = 0.013$; OR 4.2, 95% CI: 1.2, 14.5), ASD (4.7% vs. 1.0%, $p = 0.013$; OR 4.2, 95% CI: 1.2, 14.5), any neurodevelopmental disorder (i.e., learning disability, ADHD or ASD) (10.5% vs. 3.1%, $p < 0.001$; OR 3.7, 95% CI: 1.7, 7.9) and any chronic illness (44.0% vs. 25.0%, $p < 0.001$; OR 2.4, 95% CI: 1.7, 3.3). No significant differences were observed with regard to cancer, chronic fatigue, conduct disorder, Crohn's disease, depression, Types 1 or 2 diabetes, encephalopathy, epilepsy, hearing loss, high blood pressure, inflammatory bowel disease, juvenile rheumatoid arthritis, obesity, seizures, Tourette's syndrome, or services received under the Individuals with Disabilities Education Act (Table 3).

Partial versus full vaccination

Partially vaccinated children had an intermediate position between the fully vaccinated and unvaccinated in regard to several but not all health outcomes. For instance, as shown in Table 4, the partially vaccinated had an intermediate (apparently detrimental) position in terms of allergic rhinitis, ADHD, eczema, and learning disability.

Gender differences in chronic illness

Among the vaccinated (combining partially and fully vaccinated children), boys were more likely than girls to be diagnosed with a chronic condition – significantly so in the case of allergic rhinitis (13.9% vs. 7.2%, $p = 0.03$; OR 2.1, 95% CI: 1.1, 4.1), ASD (7.7% vs. 1.9%, $p = 0.006$; OR 4.3, 95% CI: 1.4, 13.2), and any neurodevelopmental disorder (14.4% vs. 6.7%, $p = 0.01$; OR 2.3, 95% CI: 1.2, 4.6) (Table 5).

Use of medications and health services

The vaccinated (combining the partially and fully vaccinated) were significantly more likely than the unvaccinated to use medication for allergies (20.0% vs. 1.2%, $p < 0.001$; OR 21.5, 95% CI: 6.7, 68.9), to have used antibiotics in the past 12 months (30.8% vs. 15.4%, $p < 0.001$; OR 2.4, 95% CI: 1.6, 3.6), and to have used fever medications at least once (90.7% vs. 67.8%, $p < 0.001$; OR 4.6, 95% CI: 3.0, 7.1). The vaccinated were also more likely to have seen a doctor for a routine checkup in the past 12 months (57.6% vs. 37.2%, $p < 0.001$; OR 2.3, 95% CI: 1.7, 3.2), visited a dentist during the past year (89.4% vs. 80.5%, $p < 0.001$; OR 2.0, 95% CI: 1.3, 3.2), visited a doctor or clinic due to illness in the past year (36.0% vs. 16.0%, $p < 0.001$; OR 3.0, 95% CI: 2.0, 4.4), been fitted with ventilation ear tubes (3.0% vs. 0.4%, $p = 0.018$; OR 8.0, 95% CI: 1.0, 66.1), and spent one or more nights in a hospital (19.8% vs. 12.3%, $p = 0.012$; OR 1.8, 95% CI: 1.1, 2.7) (Table 6).

Table 1. Characteristics of the respondents*

	Mean (SD) ^a
Age (n=407)	40.59 (6.7)
	Number (%) ^a
Race	
White	382 (92.5%)
Non-White	21 (7.6%)
Total	413
Education	
High School Graduate or Less	35 (8.5%)
Some College	114 (27.5%)
College Graduate	187 (45.2%)
Post-Graduates	78 (18.5%)
Total	414
Total Gross Household Income	
< \$49,999	123 (30.8%)
\$50,000-100,000	182 (45.5%)
> \$100,000	95 (23.8%)
Total	400
Religious Affiliation	
Christianity	375 (91.2%)
Non-Christianity	36 (8.8%)
Total	411
Marital Status	
Married	386 (93.7%)
Not Married	26 (6.3%)
Total	412

*Missing observations are excluded.

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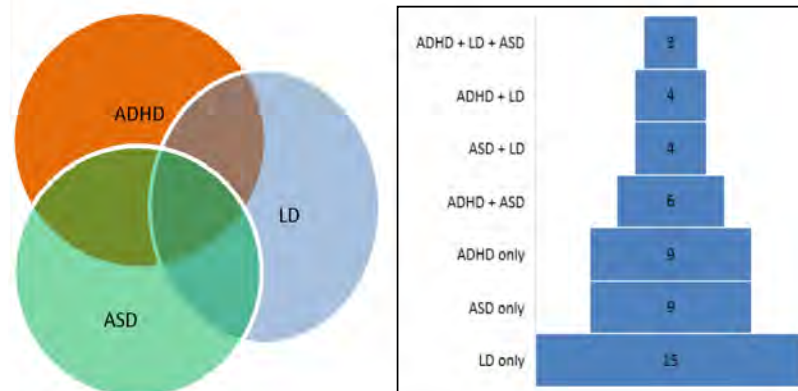


Figure 1. The overlap and distribution of physician-diagnosed neurodevelopmental disorders, based on mothers' reports

Table 2. Vaccination status and health outcomes – Acute Conditions

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Chickenpox						
Yes	32 (7.9%)	66 (25.3%)	98 (14.7%)	38.229	< 0.001	0.26 (0.2 - 0.4)
No	373 (92.1%)	195 (74.7%)	568 (85.3%)			
Otitis media						
Yes	80 (19.8%)	16(5.8%)	96 (14.4%)	26.643	< 0.001	3.8 (2.1 - 6.6)
No	325 (80.2%)	245 (94.2%)	507 (85.6%)			
Pneumonia						
Yes	26 (6.4%)	3 (1.2%)	29 (4.4%)	10.585	< 0.001	5.9 (1.8 - 19.7)
No	379 (93.6%)	258 (98.8%)	637 (95.6%)			
Whooping cough						
Yes	10 (2.5%)	22 (8.4%)	32 (4.8%)	12.326	< 0.001	0.3 (0.1 - 0.6)
No	395 (97.5%)	239 (91.6%)	634 (95.2%)			
Rubella						
Yes	1 (0.3%)	5 (1.9%)	6 (0.9%)	4.951	0.037	0.1 (0.01 - 1.1)
No	404 (99.6%)	256 (98.1%)	660 (99.1%)			

Table 3. Vaccination status and health outcomes – Chronic Conditions

Chronic Disease	Vaccinated (n=405)	Unvaccinated (n=261)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis					
Yes	42 (10.4%)	1 (0.4%)	26.21	< 0.001	30.1 (4.1 - 219.3)
No	363 (89.6%)	260 (99.6%)			
Allergies					
Yes	90 (22.2%)	18 (6.9%)	29.44	< 0.001	3.9 (2.3 - 6.6)
No	315 (77.9%)	243 (93.1%)			
ADHD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
ASD					
Yes	19 (4.7%)	3 (1.0%)	6.23	0.013	4.2 (1.2 - 14.5)
No	386 (95.3%)	258 (99.0%)			
Eczema (atopic dermatitis)					
Yes	38 (9.5%)	9 (3.6%)	8.522	0.035	2.9 (1.4 - 6.1)
No	367 (90.5%)	252 (96.4%)			
Learning Disability					
Yes	23 (5.7%)	3 (1.2%)	8.6803	0.003	5.2 (1.6 - 17.4)
No	382 (94.3%)	258 (98.9%)			
Neurodevelopment Disorder					
Yes	42 (10.5%)	8 (3.1%)	12.198	< 0.001	3.7 (1.7 - 7.9)
No	313 (89.5%)	253 (96.9%)			
Any Chronic Condition					
Yes	178 (44.0%)	65 (24.9%)	24.8456	< 0.001	2.4 (1.7 - 3.3)
No	227 (56.0%)	196 (75.1%)			

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Table 4. Partial versus full vaccination and chronic health conditions

	Unvaccinated (n=261)	Partially Vaccinated (n=208)	Fully Vaccinated (n=197)	Total (n=666)	Chi-Square	P-value
Chronic Conditions						
Allergic rhinitis						
Yes	1 (0.4%)	17 (8.2%)	25 (12.7%)	43 (6.5%)	29.6306	< 0.001
No	260 (99.6%)	191 (91.8%)	172 (87.3%)	623 (93.5%)		
Allergies						
Yes	18 (6.9%)	47 (22.6%)	43 (21.8%)	108 (16.2%)	27.4819	< 0.001
No	243 (93.1%)	161 (77.4%)	154 (78.2%)	558 (83.8%)		
ADHD						
Yes	3 (1.2%)	8 (3.9%)	11 (5.6%)	22 (3.3%)	7.1900	0.075
No	258 (98.8%)	200 (96.1%)	186 (94.4%)	644 (96.7%)		
ASD						
Yes	3 (1.2%)	11 (5.3%)	8 (4.6%)	22 (3.3%)	6.7109	0.034
No	258 (98.8%)	197 (94.7%)	189 (95.4%)	644 (96.7%)		
Eczema (atopic dermatitis)						
Yes	9 (3.5%)	18 (8.7%)	20 (10.2%)	47 (7.1%)	8.8683	0.012
No	252 (96.5%)	190 (91.3%)	177 (89.8%)	619 (92.9%)		
Learning Disability						
Yes	3 (1.2%)	11 (5.3%)	12 (6.1%)	26 (3.9%)	8.8541	0.012
No	258 (98.8%)	197 (94.7%)	185 (93.9%)	640 (96.1%)		
NDD						
Yes	8 (3.1%)	21 (10.1%)	21 (10.7%)	50 (7.5%)	12.2443	0.002
No	253 (96.9%)	187 (89.9%)	176 (89.3%)	616 (92.5%)		
Any Chronic Condition						
Yes	65 (24.9%)	94 (45.2%)	84 (42.6%)	243 (36.5%)	25.1301	< 0.001
No	196 (75.1%)	114 (54.8%)	113 (57.4%)	423 (63.5%)		

Table 5. Chronic conditions and gender among vaccinated children

	Male (n=194)	Female (n=209)	Total (n=403)	Chi-square	P-value	Odds Ratio (95% CI)
Allergic rhinitis						
Yes	27 (13.9%)	15 (7.2%)	42 (10.4%)	4.8964	0.0269	2.1 (1.1 - 4.1)
No	167 (86.1%)	194 (92.8%)	361 (90.0%)			
Allergies						
Yes	50 (25.8%)	40 (19.1%)	90 (22.3%)	2.5531	0.1101	1.5 (0.91 - 2.4)
No	144 (74.2%)	168 (80.9%)	313 (77.7%)			
ADHD						
Yes	13 (6.7%)	6 (2.9%)	19 (4.7%)	3.2856	0.0699	2.4 (0.90 - 6.5)
No	181 (93.3%)	203 (97.1%)	384 (95.3%)			
ASD						
Yes	15 (7.7%)	4 (1.9%)	19 (4.7%)	7.5810	0.0059	4.3 (1.4 - 13.2)
No	178 (92.3%)	205 (98.1%)	384 (95.3%)			
Eczema						
Yes	19 (9.89%)	19 (9.1%)	38 (9.4%)	0.0582	0.8094	1.1 (0.6 - 2.1)
No	175 (90.2%)	190 (90.9%)	365 (90.6%)			
Learning Disability						
Yes	14 (7.2%)	9 (4.3%)	23 (5.7%)	1.5835	0.2083	1.7 (0.7 - 4.1)
No	180 (92.8%)	200 (95.7%)	380 (94.3%)			
NDD						
Yes	28 (14.4%)	14 (6.7%)	42 (10.4%)	6.4469	0.0111	2.3 (1.2 - 4.6)
No	166 (85.6%)	195 (93.3%)	361 (89.6%)			
Any Chronic Condition						
Yes	94 (48.5%)	83 (39.7%)	177 (43.9%)	3.1208	0.0773	1.4 (1.0 - 2.1)
No	100 (51.5%)	126 (60.3%)	226 (56.1%)			

Factors associated with neurodevelopmental disorders

The second aim of the study focused on a specific health outcome and was designed to determine whether vaccination was associated with neurodevelopmental disorders (NDD) and, if so, whether the

association remained significant after adjustment for other measured factors. As noted, because of the relatively small numbers of children with specific diagnoses, NDD was a derived variable combining children with a diagnosis of one or more of ASD, ADHD and a learning disability. The close association and overlap of these diagnoses in the

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Table 6. Vaccination status, medication use and health services utilization

	Vaccinated (n=405)	Unvaccinated (n=261)	Total (n=666)	Chi-square	P-value	Odds Ratio (95% CI)
Medication Use						
Medication for Allergy						
Yes	81 (20.0%)	3 (1.2%)	84 (12.6%)	51.170	< 0.001	21.5 (6.7 - 68.9)
No	324 (80.0%)	258 (98.8%)	582 (87.4%)			
Used antibiotics in the past 12 months						
Yes	124 (30.8%)	40 (15.4%)	164 (24.7%)	20.092	< 0.001	2.4 (1.6 - 3.6)
No	279 (69.2%)	220 (84.6%)	499 (75.3%)			
Used fever medication 1+ times						
Yes	350 (90.7%)	173 (67.8%)	523 (81.6%)	53.288	< 0.001	4.6 (3.0 - 7.1)
No	36 (9.3%)	82 (32.2%)	118 (18.4%)			
Using fitted ear drainage tubes						
Yes	12 (3.0%)	1 (0.4%)	13 (2.0%)	5.592	0.018	8.0 (1.0 - 66.1)
No	389 (97.0%)	260 (99.6%)	649 (98.0%)			
Used medication for ADHD						
Yes	7 (1.7%)	3 (1.2%)	10 (1.5%)	0.346	0.556	-
No	398 (98.3%)	256 (98.8%)	654 (98.5%)			
Used medication for Seizures						
Yes	4 (1.0%)	1 (0.4%)	5 (0.8%)	0.769	0.653	-
No	400 (99.0%)	258 (99.6%)	658 (99.2%)			
Health Services Utilization						
Emergency Department visit in the past 12 months						
Yes	38 (9.5%)	23 (9.0%)	61 (9.3%)	0.047	0.828	-
No	364 (90.5%)	234 (91.0%)	598 (90.7%)			
Sick visit to doctor in the past year						
Yes	145 (36.0%)	41 (16.0%)	186 (28.2%)	31.096	< 0.001	3.0 (2.0 - 4.4)
No	258 (64.0%)	216 (84.0%)	474 (71.8%)			
Ever spent one or more nights in the hospital						
Yes	80 (19.8%)	32 (12.3%)	112 (16.8%)	6.267	0.012	1.8 (1.1 - 2.7)
No	325 (80.2%)	228 (87.7%)	553 (83.2%)			
Seen doctor for checkup in past 12 months						
Yes	233 (57.6%)	97 (37.2%)	330 (49.6%)	26.336	< 0.001	2.3 (1.7 - 3.2)
No	172 (42.4%)	164 (62.8%)	336 (50.4%)			
Seen dentist in the past 12 months						
Yes	362 (89.4%)	210 (80.5%)	572 (85.9%)	10.424	< 0.001	2.0 (1.3 - 3.2)
No	43 (10.6%)	51 (19.5%)	94 (14.1%)			

study is shown in the figure above (Figure 1). The figure shows that the single largest group of diagnoses was learning disability (n=15) followed by ASD (n=9), and ADHD (n=9), with smaller numbers comprising combinations of the three diagnoses.

Unadjusted analysis

Table 7 shows that the factors associated with NDD in unadjusted logistic regression analyses were: vaccination (OR 3.7, 95% CI: 1.7, 7.9); male gender (OR 2.1, 95% CI: 1.1, 3.8); adverse environment, defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory (OR 2.9, 95% CI: 1.1, 7.4); maternal use of antibiotics during pregnancy (OR 2.3, 95% CI: 1.1, 4.8); and preterm birth (OR 4.9, 95% CI: 2.4, 10.3). Two factors that almost reached statistical significance were vaccination during pregnancy (OR 2.5, 95% CI: 1.0, 6.3) and three or more fetal ultrasounds (OR 3.2, 95% CI: 0.92, 11.5). Factors that were not associated with NDD in this study included mother's education, household income, and religious affiliation; use of acetaminophen, alcohol, and antacids during pregnancy; gestational diabetes; preeclampsia; Rhogham shot during pregnancy; and breastfeeding (data not shown).

Adjusted analysis

After adjustment for all other significant factors, those that remained significantly associated with NDD were: vaccination (OR 3.1, 95% CI: 1.4, 6.8); male gender (OR 2.3, 95% CI: 1.2, 4.3); and preterm birth (OR 5.0, 95% CI: 2.3, 11.1). The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors.

In a final adjusted model designed to test for this possibility, controlling for the interaction of preterm birth and vaccination, the following factors remained significantly associated with NDD: vaccination (OR 2.5, 95% CI: 1.1, 5.6), nonwhite race (OR 2.4, 95% CI: 1.1, 5.4), and male gender (OR 2.3, 95% CI: 1.2, 4.4). Preterm birth itself, however, was not significantly associated with NDD, whereas the combination (interaction) of preterm birth and vaccination was associated with 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5) (Table 8).

Discussion

Following a recommendation of the Institute of Medicine [19] for studies comparing the health outcomes of vaccinated and unvaccinated

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Table 7. Unadjusted analysis of potential risk factors for neurodevelopmental disorders

Vaccination Status	NDD			Chi-Square	P-value	OR (95% CI)**
	Yes (N=50)	No (N=616)	Total* (N=666)			
Vaccinated	42	363	405	12.198	<0.001	3.7 (1.7 - 7.9)
Not Vaccinated	8	253	261			Ref
Race						
Non-White	9	71	80	1.8208	0.177	1.7 (0.7 - 3.6)
White	41	544	585			Ref
Child's Gender						
Male	32	283	315	5.9471	0.015	2.1 (1.1 - 3.8)
Female	18	331	349			Ref
Adverse Environment						
Yes	6	27	33	5.8706	0.053	2.9 (1.1 - 7.4)
No	40	523	563			Ref
Do not know	4	66	70			0.8 (0.3 - 2.3)
Medication during Pregnancy - Antibiotics						
Yes	10	61	71	4.950	0.026	2.3 (1.1 - 4.8)
No	40	555	595			Ref
Medication during Pregnancy - Vaccinated						
Yes	6	32	38	3.965	0.057	2.5 (1.0 - 6.3)
No	44	583	627			Ref
Preterm birth						
Yes	12	37	49	22.910	< 0.001	4.9 (2.4 - 10.3)
No	38	578	616			Ref
Ultrasound						
None	3	71	74	5.898	0.052	Ref
1-3 times	30	419	449			1.7 (0.5 - 5.7)
> 3 times	17	124	141			3.2 (0.92 - 11.5)

*Numbers may not add to column totals due to missing or incomplete data.

**Note that Odds Ratios are the cross-product ratios of the entries in the 2-by-2 tables, and are an estimate of the relative incidence (or risk) of the outcome associated with the exposure factor.

Table 8. Adjusted logistic regression analyses of risk factors and NDD*

	Adjusted Model (Model 1)	Adjusted Model with Interaction (Model 2)
Vaccination Status		
Vaccinated	3.1 (1.4 - 6.8)	2.5 (1.1 - 5.6)
Not Vaccinated	Ref	Ref
Race		
Non-White	2.3 (1.0 - 5.2)	2.4 (1.1 - 5.4)
White	Ref	Ref
Child's Gender		
Male	2.3 (1.2 - 4.3)	2.3 (1.2 - 4.4)
Female	Ref	Ref
Preterm birth		
Yes	5.0 (2.3 - 11.1)	NS
No	Ref	
Preterm birth and Vaccination interaction		
No interaction		Ref
Preterm and Vaccinated	Not in the model	6.6 (2.8 - 15.5)

*Number of observation read 666, number of observations used 629. NDD=47, Not NDD = 582

children, this study focused on homeschool children ages 6 to 12 years based on mothers' anonymous reports of pregnancy-related conditions, birth histories, physician-diagnosed illnesses, medications and healthcare use. Respondents were mostly white, married, and college-educated, upper income women who had been contacted and

invited to participate in the study by the leaders of their homeschool organizations. Data from the survey were also used to determine whether vaccination was associated specifically with NDDs, a derived diagnostic category combining children with the diagnoses of learning disability, ASD and/or ADHD.

With regard to acute and chronic conditions, vaccinated children were significantly less likely than the unvaccinated to have had chickenpox and pertussis but, contrary to expectation, were significantly more likely to have been diagnosed with otitis media, pneumonia, allergic rhinitis, eczema, and NDD. The vaccinated were also more likely to have used antibiotics, allergy and fever medications; to have been fitted with ventilation ear tubes; visited a doctor for a health issue in the previous year, and been hospitalized. The reason for hospitalization and the age of the child at the time were not determined, but the latter finding appears consistent with a study of 38,801 reports to the VAERS of infants who were hospitalized or had died after receiving vaccinations. The study reported a linear relationship between the number of vaccine doses administered at one time and the rate of hospitalization and death; moreover, the younger the infant at the time of vaccination, the higher was the rate of hospitalization and death [55]. The hospitalization rate increased from 11% for 2 vaccine doses to 23.5% for 8 doses ($r^2 = 0.91$), while the case fatality rate increased significantly from 3.6% for those receiving from 1-4 doses to 5.4 % for those receiving from 5-8 doses.

In support of the possibility that the number of vaccinations received could be implicated in risks of associated chronic illness, a

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comparison of unvaccinated, partially and fully vaccinated children in the present study showed that the partially vaccinated had increased but intermediate odds of chronic disease, between those of unvaccinated and fully vaccinated children, specifically for allergic rhinitis, ADHD, eczema, a learning disability, and NDD as a whole.

The national rates of ADHD and LD are comparable to those of the study. The U.S. rate of ADHD for ages 4-17 (twice the age range of children than the present study), is 11% [31]. The study rate of ADHD for ages 6 to 12 is 3.3%, and 4.7% when only vaccinated children are included. The national LD rate is 5% [32], and the study data show a rate of LD of 3.9% for all groups, and 5.6% when only vaccinated children are included. However, the ASD prevalence of 2.24% from a CDC parent survey is lower than the study rate of 3.3%. Vaccinated males were significantly more likely than vaccinated females to have been diagnosed with allergic rhinitis, and NDD. The percentage of vaccinated males with an NDD in this study (14.4%) is consistent with national findings based on parental responses to survey questions, indicating that 15% of U.S. children ages 3 to 17 years in the years 2006-2008 had an NDD [28]. Boys are also more likely than girls to be diagnosed with an NDD, and ASD in particular [29].

Vaccination was strongly associated with both otitis media and pneumonia, which are among the most common complications of measles infection [56,57]. The odds of otitis media were almost four-fold higher among the vaccinated (OR 3.8, 95% CI: 2.1, 6.6) and the odds of myringotomy with tube placement were eight-fold higher than those of unvaccinated children (OR 8.0, 95% CI: 1.0, 66.1). Acute otitis media (AOM) is a very frequent childhood infection, accounting for up to 30 million physician visits each year in the U.S., and the most common reason for prescribing antibiotics for children [58,59]. The incidence of AOM peaks at ages 3 to 18 months and 80% of children have experienced at least one episode by 3 years of age. Rates of AOM have increased in recent decades [60]. Worldwide, the incidence of AOM is 10.9%, with 709 million cases each year, 51% occurring in children under 5 years of age [61]. Pediatric AOM is a significant concern in terms of healthcare utilization in the U.S., accounting for \$2.88 billion in annual health care costs [62].

Numerous reports of AOM have been filed with VAERS. A search of VAERS for "Cases where age is under 1 and onset interval is 0 or 1 or 2 or 3 or 4 or 5 or 6 or 7 days and Symptom is otitis media" [63] revealed that 438,573 cases were reported between 1990 and 2011, often with fever and other signs and symptoms of inflammation and central nervous system involvement. One study [64] assessed the nasopharyngeal carriage of *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis* during AOM in fully immunized, partly immunized children with 0 or 1 dose of Pneumococcal Conjugate Vaccine-7 (PCV7), and "historical control" children from the pre-PCV-7 era, and found an increased frequency of *M. catarrhalis* colonization in the vaccinated group compared to the partly immunized and control groups (76% vs. 62% and 56%, respectively). A high rate of *Moraxella catarrhalis* colonization is associated with an increased risk of AOM [65].

Successful vaccination against pneumococcal infections can lead to replacement of the latter in the nasopharyngeal niche by nonvaccine pneumococcal serotypes and disease [66]. Vaccination with PCV-7 has a marked effect on the complete microbiota composition of the upper respiratory tract in children, going beyond shifts in the distribution of pneumococcal serotypes and known potential pathogens and resulting in increased anaerobes, gram-positive bacteria and gram-negative bacterial species. PCV-7 administration also correlates highly with the emergence and expansion of oropharyngeal types of species.

These observations have suggested that eradication of vaccine serotype pneumococci can be followed by colonization of other bacterial species in the vacant nasopharyngeal niche, leading to disequilibria of bacterial composition (dysbiosis) and increased risks of otitis media. Long-term monitoring has been recommended as essential for understanding the full implications of vaccination-induced changes in microbiota structure [67].

The second aim of the paper focused on a specific health outcome and sought to determine whether vaccination remained associated with neurodevelopmental disorders (NDD) after controlling for other measured factors. After adjustment, the factors that remained significantly associated with NDD were vaccination, nonwhite race, male gender, and preterm birth. The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors. This was shown in a final adjusted model with interaction (controlling for the interaction of preterm birth with vaccination). In this model, vaccination, nonwhite race and male gender remained associated with NDD, whereas preterm birth itself was no longer associated with NDD. However, preterm birth combined with vaccination was associated with a 6.6-fold increased odds of NDD.

In summary, vaccination, nonwhite race, and male gender were significantly associated with NDD after controlling for other factors. Preterm birth, although significantly associated with NDD in unadjusted and adjusted analyses, was no longer associated with NDD in the final model with interaction. However, preterm birth and vaccination combined was strongly associated with NDD in the final adjusted model with interaction, more than doubling the odds of NDD compared to vaccination alone. Preterm birth has long been known as a major factor for NDD [68,69], but since preterm infants are routinely vaccinated, the separate effects of preterm birth and vaccination have not been examined. The present study suggests that vaccination could be a contributing factor in the pathogenesis of NDD but also that preterm birth by itself may have a lesser or much reduced role in NDD (defined here as ASD, ADHD and/or a learning disability) than currently believed. The findings also suggest that vaccination coupled with preterm birth could increase the odds of NDD beyond that of vaccination alone.

Potential limitations

We did not set out to test a specific hypothesis about the association between vaccination and health. The aim of the study was to determine whether the health outcomes of vaccinated children differed from those of unvaccinated homeschool children, given that vaccines have nonspecific effects on morbidity and mortality in addition to protecting against targeted pathogens [11]. Comparisons were based on mothers' reports of pregnancy-related factors, birth histories, vaccinations, physician-diagnosed illnesses, medications, and the use of health services. We tested the null hypothesis of no difference in outcomes using chi-square tests, and then used Odds Ratios and 96% Confidence Intervals to determine the strength and significance of the association.

If the effects of vaccination on health were limited to protection against the targeted pathogens, as is assumed to be the case [21], no difference in outcomes would be expected between the vaccinated and unvaccinated groups except for reduced rates of the targeted infectious diseases. However, in this homogeneous sample of 666 children there were striking differences in diverse health outcomes between the groups. The vaccinated were less likely to have had chickenpox or whooping cough, as expected, but more likely to have been diagnosed with pneumonia and ear infections as well as allergies and NDDs.

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What credence can be given to the findings? This study was not intended to be based on a representative sample of homeschool children but on a convenience sample of sufficient size to test for significant differences in outcomes. Homeschoolers were targeted for the study because their vaccination completion rates are lower than those of children in the general population. In this respect our pilot survey was successful, since data were available on 261 unvaccinated children.

To eliminate opportunities for subjectivity or opinion in the data, only factual information was requested and the questions involved memorable events such as physician-diagnosed diseases in a child. With regard to minimizing potential bias in the information provided by mothers, all communications with the latter emphasized neutrality regarding vaccination and vaccine safety. To minimize recall bias, respondents were asked to use their child's vaccination records. To enhance reliability, closed-ended questions were used and each set of questions had to be completed before proceeding to the next. To enhance validity, parents were asked to report only physician-diagnosed illnesses.

Mothers' reports could not be validated by clinical records because the survey was designed to be anonymous. However, self-reports about significant events provide a valid proxy for official records when medical records and administrative data are unavailable [70]. Had mothers been asked to provide copies of their children's medical records it would no longer have been an anonymous study and would have resulted in few completed questionnaires. We were advised by homeschool leaders that recruitment efforts would have been unsuccessful had we insisted on obtaining the children's medical records as a requirement for participating in the study.

A further potential limitation is under-ascertainment of disease in unvaccinated children. Could the unvaccinated have artificially reduced rates of illness because they are seen less often by physicians and would therefore have been less likely to be diagnosed with a disease? The vaccinated were indeed more likely to have seen a doctor for a routine checkup in the past 12 months (57.5% vs. 37.1%, $p < 0.001$; OR 2.3, 95% CI: 1.7, 3.1). Such visits usually involve vaccinations, which non-vaccinating families would be expected to refuse. However, fewer visits to physicians would not necessarily mean that unvaccinated children are less likely to be seen by a physician if their condition warranted it. In fact, since unvaccinated children were more likely to be diagnosed with chickenpox and whooping cough, which would have involved a visit to the pediatrician, differences in health outcomes are unlikely to be due to under-ascertainment.

Strengths of the study include the unique design of the study, involving homeschool mothers as respondents, and the relatively large sample of unvaccinated children, which made it possible to compare health outcomes across the spectrum of vaccination coverage. Recruitment of biological mothers as respondents also allowed us to test hypotheses about the role of pregnancy-related factors and birth history as well as vaccination in NDD and other specific conditions. In addition, this was a within-group study of a demographically homogeneous population of mainly white, higher-income and college-educated homeschooling families in which the children were all 6-12 years of age. Information was provided anonymously by biological mothers, obviously well-informed about their own children's vaccination status and health, which likely increased the validity of the reports.

Conclusions

Assessment of the long-term effects of the vaccination schedule on morbidity and mortality has been limited [71]. In this pilot study of

vaccinated and unvaccinated homeschool children, reduced odds of chickenpox and whooping cough were found among the vaccinated, as expected, but unexpectedly increased odds were found for many other physician-diagnosed conditions. Although the cross-sectional design of the study limits causal interpretation, the strength and consistency of the findings, the apparent "dose-response" relationship between vaccination status and several forms of chronic illness, and the significant association between vaccination and NDDs all support the possibility that some aspect of the current vaccination program could be contributing to risks of childhood morbidity. Vaccination also remained significantly associated with NDD after controlling for other factors, whereas preterm birth, long considered a major risk factor for NDD, was not associated with NDD after controlling for the interaction between preterm birth and vaccination. In addition, preterm birth coupled with vaccination was associated with an apparent synergistic increase in the odds of NDD above that of vaccination alone. Nevertheless, the study findings should be interpreted with caution. First, additional research is needed to replicate the findings in studies with larger samples and stronger research designs. Second, subject to replication, potentially detrimental factors associated with the vaccination schedule should be identified and addressed and underlying mechanisms better understood. Such studies are essential in order to optimize the impact of vaccination of children's health.

Competing Interests

The authors declare that they have no financial interests that had any bearing on any aspect of the conduct or conclusions of the study and the submitted manuscript.

Author contributions

AM designed the study, contributed to data analysis and interpretation, and drafted the paper. BR designed the study, contributed to data collection, and edited the paper. AB contributed to data analyses and edited the paper. BJ contributed to data analyses and editing. All authors read and approved the final version of the paper.

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Disclaimer

This study was approved by the Institutional Review Board of Jackson State University and completed prior to Dr. Mawson's tenure-track appointment at Jackson State University.

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Common variants associated with general and MMR vaccine-related febrile seizures

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Abstract

Febrile seizures represent a recognized serious adverse event following measles, mumps, and rubella (MMR) vaccination. We conducted a series of genome-wide association scans comparing children with MMR-related febrile seizures, children with febrile seizures unrelated to

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AUTHOR CONTRIBUTIONS

B.F., B.P., F.G., M.M., and A.H. designed the project and drafted the manuscript. B.P., H.S., M.V. and A.H. planned and performed register data acquisition, informatics, and phenotypic characterization. B.F., F.G., and L.C. carried out the statistical genetics and bioinformatics analyses. M.V.H. and D.H. performed sampling, whole-genome amplification and genotyping. J.L.E. and J.W.S. designed and performed the cell-based overexpression experiments and analysed the data. T.W., F.H., and L.Y.J. designed and performed the electrophysiology experiments and analysed the data. All authors contributed to the final manuscript.

COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

vaccination, and controls with no history of febrile seizures. Two loci were distinctly associated with MMR-related febrile seizures, harboring the interferon-stimulated gene *IFI44L* (rs273259; $P = 5.9 \times 10^{-12}$ vs. controls; $P = 1.2 \times 10^{-9}$ vs. MMR-unrelated febrile seizures) and the measles virus receptor *CD46* (rs1318653; $P = 9.6 \times 10^{-11}$ vs. controls; $P = 1.6 \times 10^{-9}$ vs. MMR-unrelated febrile seizures). Furthermore, four loci were associated with febrile seizures in general implicating the sodium channel genes *SCN1A* (rs6432860; $P = 2.2 \times 10^{-16}$) and *SCN2A* (rs3769955; $P = 3.1 \times 10^{-10}$), a TMEM16 family gene (*TMEM16C*; rs114444506; $P = 3.7 \times 10^{-20}$), and a region associated with magnesium levels (12q21.33; rs11105468; $P = 3.4 \times 10^{-11}$). Finally, functional relevance of *TMEM16C* was demonstrated with electrophysiological experiments in wild-type and knockout rats.

Vaccination is one of the most effective public health interventions and modern vaccines have an excellent safety record. However, on rare occasions some individuals experience serious adverse events. Investigating the underlying causes of such events is essential to maintain public confidence in vaccination and may help improve vaccine safety. Fever is a common reaction to immunization, and febrile seizures occasionally occur after vaccination, especially with live-virus vaccines such as the measles, mumps, and rubella (MMR) vaccine. Although generally well-tolerated, MMR vaccination almost triples the risk of febrile seizures in the second week following vaccination, resulting in an estimated 3 to 16 additional febrile seizure cases per 10,000 vaccinated children^{1, 2}. Overall, febrile seizures occur in 2–5% of children of European ancestry before 5 years of age³, often induced by fever from viral infections⁴.

Genetic studies of epileptic disorders with concomitant febrile seizures have identified a number of risk variants, particularly in ion channel genes^{5, 6}. However, the vast majority of children with febrile seizures do not develop epilepsy⁷, and while family and twin studies suggest a strong genetic component to isolated febrile seizures^{8–10}, little is known about specific genetic variants. It is also unknown whether distinct variants influence the risk of febrile seizures occurring as an adverse effect of MMR vaccination, or whether the MMR vaccine is just one of many possible stimuli that may trigger febrile seizures in susceptible individuals.

Here, we address these questions using a series of genome-wide association scans and replication genotyping, cell-based overexpression assays, and electrophysiological recordings of brain slices from wild-type and knockout rats.

RESULTS

Our study design is illustrated in Supplementary Figure 1. In the discovery stage, we conducted four genome-wide association scans: (1) MMR-related febrile seizures versus controls (2) MMR-related febrile seizures versus MMR-unrelated febrile seizures; (3) MMR-unrelated febrile seizures versus controls; and (4) febrile seizures overall versus controls. Sample characteristics and inclusion criteria are given in Supplementary Table 1. After imputation based on reference data from the 1000 Genomes Project, approximately 8.1 million variants were included in each of the four association scans. Genomic inflation factors were 1.01, 1.00, 1.02, and 1.03 for the four scans, respectively, indicating minimal

population stratification. Quantile-quantile and Manhattan plots are shown in Supplementary Figure 2. Based on the discovery stage results, we selected 23 SNPs representing 16 loci for replication stage genotyping (Supplementary Fig. 3). Furthermore, we conducted analyses conditioning on the selected SNPs, but no additional SNPs fulfilling the selection criteria were identified. We applied a genome-wide significance threshold of $P < 1.25 \times 10^{-8}$ since four association scans were conducted. Six independent genetic loci were replicated and reached genome-wide significance in one or more of the combined analyses (Table 1 and Supplementary Table 2).

Distinct associations for MMR-related febrile seizures

Four loci reached genome-wide significance in the analysis of MMR-related febrile seizures versus controls. Out of these, two also reached genome-wide significance in the analysis of MMR-related febrile seizures versus MMR-unrelated febrile seizures while not showing any effect in the analysis of MMR-unrelated febrile seizures versus controls (Table 1). In agreement with this, a genetic risk score based on these two loci showed no association in a logistic regression analysis of MMR-unrelated febrile seizures versus controls ($P = 0.42$) while being highly significant in comparisons of MMR-related febrile seizures versus controls ($P < 2 \times 10^{-16}$) and versus MMR-unrelated febrile seizures ($P < 2 \times 10^{-16}$). Both loci were thus distinctly associated with febrile seizures following MMR vaccination. We found no evidence of interaction between the two top SNPs. There was also no interaction between either of the two SNPs and the four SNPs for febrile seizures overall in Table 1 and their effect estimates were not changed by conditioning on the four top SNPs for febrile seizures overall (results not shown). We considered all 48 genotyped or imputed variants (SNP and indels) with $P < 1 \times 10^{-5}$ at these two loci and searched for functional predictions. These variants were all in linkage disequilibrium (LD) with the top SNP at the given locus (r^2 between 0.47 and 1; Supplementary Table 3).

At the first locus for MMR-related febrile seizures on chromosome 1p31.1, the associated SNPs fall in a sharply defined 45-kb LD block containing the gene *IFI44L* (Fig. 1a). Among 25 variants with $P < 1 \times 10^{-5}$, two were missense mutations (Supplementary Table 3). One of these, rs273259 (c.218A>G [p.His73Arg]; Ensembl transcript ENST00000370751), ranked among the lowest in P value at the locus and was selected for replication genotyping. It showed genome-wide significant association in MMR-related febrile seizures versus controls (odds ratio (OR) = 1.41, 95% confidence interval (CI) = 1.28–1.55; $P = 5.9 \times 10^{-12}$) and versus MMR-unrelated febrile seizures (OR = 1.42, 95% CI = 1.27–1.59; $P = 1.2 \times 10^{-9}$). It was not predicted to be damaging by MutationTaster or PolyPhen-2, but appears to affect relative levels of splice isoforms. The risk allele, rs273259-A, for MMR-related febrile seizures corresponds to decreased expression of exon 2 (of ENST00000370751 transcript), in which it resides, in lymphoblastoid cell lines¹¹ and corresponds to decreased expression of *IFI44L-001* (ENST00000370751) and increased expression of *IFI44L-002* (ENST00000486882) relative to other transcripts¹¹. In peripheral blood, rs273259-A is associated with decreased expression of the neighboring gene *IFI44*¹². *IFI44L* and *IFI44* belong to the group of interferon-stimulated genes (ISGs), and are both transcriptionally induced by type I interferon signaling. The expression of *IFI44L* (in dendritic cells) is significantly up-regulated following measles virus infection¹³. In a large-

scale antiviral screen of ISGs, *IFI44L* modestly inhibited hepatitis C virus replication¹⁴. We tested whether *IFI44L* impacts replication of a recombinant measles virus expressing green fluorescent protein (GFP). Using a lentiviral ectopic expression assay¹⁴, three tested *IFI44L* variants had no effect on measles virus replication in immortalized human fibroblasts lacking *STAT1* (Supplementary Fig. 4). Under these experimental conditions, *IFI44L* variants are not sufficient to confer direct antiviral protection against measles virus. Other cellular backgrounds or host factors may be important for a functional antiviral phenotype.

The most significant SNP at the second locus on chromosome 1q32.2, rs1318653 (OR = 1.43, 95% CI = 1.28–1.59; $P = 9.6 \times 10^{-11}$ versus controls and OR = 1.48, 95% CI = 1.30–1.67; $P = 1.6 \times 10^{-9}$ versus MMR-unrelated febrile seizures) lies between *CD46* and *CD34* (Fig. 1b). None of the 23 variants with $P < 1 \times 10^{-5}$ at the locus were coding, nor were they reported in the GWAS catalog or as eQTLs (Supplementary Table 3). However one of these variants, rs2724384, which is intronic in *CD46* and highly correlated with rs1318653 ($r^2 = 0.95$) has been reported in candidate gene studies to associate with immune response after MMR^{15, 16} and measles virus vaccination¹⁷. The variant rs2724384 was therefore also genotyped in the replication stage and reached genome-wide significance versus both controls and MMR-unrelated febrile seizures (Supplementary Table 2). The risk allele, rs2724384-A, for MMR-related febrile seizures corresponds to increased measles-specific IgG antibody levels^{15–17} and reduced IL-6, IFN- α , and TNF- α secretion following stimulation with vaccine-strain measles virus¹⁸. Furthermore, rs2724384-A is associated with increased expression of exons 7 and 8 of *CD46* (ENST00000358170 transcript) in lymphoblastoid cell lines as well as increased expression of *CD46-004* (ENST00000367042) relative to other transcripts and increased overall expression of the gene¹¹. *CD46* encodes a type I membrane protein that is a regulatory part of the complement system, induces proliferation and differentiation of regulatory T cells¹⁹, and acts as a cellular receptor for measles virus^{20, 21}, primarily vaccine-strain virus²².

Associations for febrile seizures in general

Variants at four loci reached genome-wide significance in the analysis of febrile seizures overall versus controls, and none of these differed between MMR-related febrile seizures and MMR-unrelated febrile seizures (Table 1 and Supplementary Table 2). A genetic risk score based on these four loci thus showed no effect in a logistic regression analysis of MMR-related febrile seizures versus MMR-unrelated febrile seizures ($P = 0.22$), but was highly significant in comparisons of MMR-related febrile seizures, MMR-unrelated febrile seizures, or febrile seizures overall versus controls ($P < 2 \times 10^{-16}$ in all three analyses). In the febrile seizures overall versus controls analysis, the 10% of children with the highest genetic risk scores were at almost 4 times higher risk than the 10% of children with the lowest risk scores (OR = 3.73, 95% CI = 3.06–4.56). We found no evidence of interaction between the four top SNPs and their effect estimates were also not changed by conditioning on the two SNPs for MMR-related febrile seizures in Table 1 (results not shown). The loci that were genome-wide significant in the febrile seizures overall versus controls analysis were also selected for genotyping in an auxiliary replication set of febrile seizures patients with 25 or more years of follow-up without any epilepsy diagnosis. Three out of four loci were replicated ($P_{\text{replication}} < 0.05$ and $P_{\text{combined}} < 1.25 \times 10^{-8}$) when using this smaller alternative

replication set (Supplementary Table 4). The febrile seizure cases in our main analysis were followed in the Danish National Patient Register until a median age of 15 years for the discovery stage cases and 10 years for the replication stage cases. In this time period 92 out of 1,999 discovery stage cases (4.6%) and 53 out of 1,443 replication stage cases (3.7%) had an epilepsy or non-febrile seizure diagnosis. We performed a sensitivity analysis excluding those cases and found very similar results compared with the main analysis (Supplementary Table 5). Next, we considered all 347 genotyped or imputed variants (SNP and indels) with $P < 1 \times 10^{-5}$ at the four loci and searched for functional predictions for these variants. Correlations with the top SNP at each locus ranged from $r^2 = 0.09$ to 1 (Supplementary Table 6).

Two loci harboring sodium channel genes

At the first locus for febrile seizures overall on chromosome 2q24.3, rs3769955 yielded the lowest P value (OR = 1.22, 95% CI = 1.15–1.30; $P = 3.1 \times 10^{-10}$). This SNP is intronic in *SCN2A* and lies in an LD block stretching into the neighboring gene *CSRNP3* (Fig. 2a). None of the 41 variants with $P < 1 \times 10^{-5}$ at the locus were coding (Supplementary Table 6), nor were they reported in the GWAS catalog or as eQTLs. *SCN2A* encodes the voltage-gated Na^+ channel alpha-subunit $\text{Na}_V1.2$, which plays an essential role in the initiation and propagation of action potentials in neurons. $\text{Na}_V1.2$ is located with high density in the axon initial segment of excitatory cortical and hippocampal neurons²³. Rare missense mutations in *SCN2A* are reported to cause benign familial neonatal and infantile seizures (BFNIS)²⁴ by a gain-of-function mechanism that increases excitability of these neurons²⁵. Furthermore, a febrile increase in temperature from 37°C to 41°C has been shown to directly increase $\text{Na}_V1.2$ channel excitability in HEK-293T cells, supporting a role for *SCN2A* in febrile seizure genesis²³.

The second locus is also on chromosome 2q24.3 in a region containing *SCN1A*, *TTC21B* and the non-coding transcripts *LOC100506124* and *LOC100506134* (Fig. 2b and Supplementary Table 6). Four SNPs at the locus were genotyped in the replication stage, all reaching genome-wide significance (Supplementary Table 2). The lowest P value was seen for rs6432860 (OR = 1.34, 95% CI = 1.25–1.43; $P = 2.2 \times 10^{-16}$), a synonymous SNP in *SCN1A* and an eQTL for *TTC21B* in the liver²⁶. Among 238 variants with $P < 1 \times 10^{-5}$ at the locus, rs7587026 was reported to associate with mesial temporal lobe epilepsy with hippocampal sclerosis with febrile seizures²⁷ in a recent GWAS meta-analysis, with the reported risk allele, rs7587026-A, corresponding to increased risk of febrile seizures in our data (Supplementary Table 6). Another associated SNP at the locus, rs3812718, affects alternative splicing of *SCN1A* in brain tissue^{27, 28}, and was significantly associated with febrile seizures in general in two relatively small sample sets, but not in a third²⁷. Again, the reported risk allele, rs3812718-A, corresponded to increased risk of febrile seizures in our data (Supplementary Table 6). *SCN1A* encodes the voltage-gated Na^+ channel alpha-subunit $\text{Na}_V1.1$, which is expressed predominantly in the axon initial segment of inhibitory interneurons²⁹. Rare mutations in *SCN1A* cause a wide spectrum of epilepsy syndromes, including genetic epilepsy with febrile seizures plus (GEFS+) and Dravet syndrome (DS, also known as severe myoclonic epilepsy of infancy)⁵, depending on the nature of the mutation and possible genetic modifiers on other genes³⁰.

In the larger region encompassing both loci, rs3769955 and rs6432860 are 660 kb apart in different LD blocks with $r^2 = 0.02$ and $D' = 0.24$ between the two SNPs based on the replication stage genotypes. Conditioning on either SNP left little residual association signal in its own LD block while only mildly attenuating the signal in the other block (Supplementary Fig. 5a,b). In an analysis conditional on both top SNPs, no SNP in the region achieved $P < 5 \times 10^{-4}$. (Supplementary Fig. 5c).

Large-effect variants at TMEM16C locus

The most significant SNP at the third locus for febrile seizures overall on chromosome 11p14.2, rs114444506 (OR = 2.09, 95% CI = 1.79–2.44; $P = 3.7 \times 10^{-20}$), lies in the first intron of the *TMEM16C* (also known as *ANO3*) splice variant *ANO3-201* (ENST00000537978) (Fig. 2c). None of the 30 variants with $P < 1 \times 10^{-5}$ at the locus were coding (Supplementary Table 6), nor were they reported in the GWAS catalog or as eQTLs. *TMEM16C* (*ANO3*) belongs to the *TMEM16* (anoctamin) protein family, a group of ten homologous transmembrane proteins that includes at least two Ca^{2+} -activated chloride channels and other members about which less is yet known³¹. Rare *TMEM16C* missense mutations have been found to segregate with autosomal dominant craniocervical dystonia and high expression of the gene in human striatum, hippocampus and cortex has been documented³². It was recently demonstrated that *Tmem16C* (*Ano3*^{-/-}) knockout rats exhibit hyperexcitability of nociceptive neurons and a decreased threshold for pain³³. Below, we investigate the potential role of *TMEM16C* in seizure genesis through electrophysiological recordings in brain slices from wild-type and knockout rats.

A locus associated with serum magnesium levels

At the fourth locus for febrile seizures overall, the top SNP, rs11105468 (OR = 1.25, 95% CI = 1.17–1.33; $P = 3.4 \times 10^{-11}$), is located in an intergenic region on chromosome 12q21.33 (Fig. 2d). All 38 variants with $P < 1 \times 10^{-5}$ at the locus were intergenic (Supplementary Table 6); none were eQTLs, but several were reported in a GWAS of serum magnesium levels, with $P = 3.8 \times 10^{-12}$ for rs11105468³⁴. For these SNPs, the allele associated with lower magnesium levels was associated with increased risk of febrile seizures in our data. It is well established that magnesium deprivation can lead to seizures in laboratory animals³⁵ and humans³⁶, and *in vitro* experiments have shown that magnesium deficiency results in spontaneous epileptiform discharges in rat hippocampal brain slices³⁷. At the molecular level, Mg^{2+} blocks the channel pore of excitatory *N*-methyl-D-aspartate (NMDA) receptors under basal conditions. The Mg^{2+} blockade is relieved by cellular depolarization thus allowing Ca^{2+} and Na^+ to enter the postsynaptic neuron as potassium exits³⁸. To explore the role of other variants associated with magnesium levels, we looked up the top SNP at all 9 confirmed and suggestive loci for serum magnesium levels³⁴, but apart from the 12q21.33 locus these loci were not associated with febrile seizures (Supplementary Table 7).

Electrophysiology, TMEM16C knockout rats

We performed electrophysiological recordings in brain slices of wild-type and *Tmem16C* knockout rats³³ to investigate potential mechanisms involving *TMEM16C* in febrile seizure genesis. Given the role of anterior hypothalamic nucleus (AHN) in thermoregulation³⁹, we

first performed whole-cell patch-clamp recordings of AHN neurons to determine the effect of *TMEM16C* on spontaneous action potential (SAP) firing patterns at different temperatures. Recordings were done in slices from postnatal day (P) 10 to 12 male rats at 33°C, 36.5°C, and 40°C, and we found a significantly lower proportion of heat sensitive neurons (increased SAP firing with increasing local brain temperature) in *Tmem16C* knockout rats compared to wild-type rats (Fig. 3, Fisher's exact test, $P = 0.005$, $n = 30$ for each group; see Supplementary Fig. 6 for the distribution and comparable membrane properties of AHN neurons from wild-type and *Tmem16C* knockout rats).

The hippocampus is often the focus of seizures; hence, we next examined whether *TMEM16C* influences hippocampal neuronal excitability. We performed whole-cell current clamp recordings of hippocampal pyramidal neurons from P14 male wild-type and *Tmem16C* knockout rats at different temperatures. Slice recordings from CA1 pyramidal neurons revealed that the resting membrane potential (V_m) is more depolarized by 4–5 mV in *Tmem16C* knock-out rats compared with wild-type controls at room temperature (Supplementary Fig. 7a, Student's t-test, $P < 0.05$, $n = 9–11$). Furthermore, current step injections revealed that neurons from knockout rats fire more action potentials than wild-type neurons at the same amount of injected current (Supplementary Fig. 7e,f). To mimic body temperature shifts in fever, we performed similar experiments at 36.5°C and 40°C and found hippocampal neurons without *Tmem16C* to display increased excitability at both temperatures (Fig. 4, two-way ANOVA, $P < 0.01$).

DISCUSSION

In this work, designed to investigate both the genetics of an adverse vaccination effect and of febrile seizures, we demonstrated that two loci were distinctly associated with febrile seizures as an adverse event following MMR vaccination and that four additional loci were associated with febrile seizures in general. Further, in the absence of *TMEM16C*, hypothalamic neurons were less responsive to heat, which could lead to impaired homeostatic control when body temperature rises, and hippocampal neurons became hyperexcitable, which could possibly contribute to febrile seizure genesis.

Our findings, implicating loci harboring the innate immune system genes *IFI44L* and *CD46*, represent a first step in understanding the biological mechanisms underlying febrile seizures as an adverse effect of MMR vaccination. An important next step will be to elucidate the pathways by which the identified variants influence the immune response and contribute to the development of fever, seizures, or both. One possibility might be that the pathogenic mechanism of MMR-related febrile seizures involves two independent steps: febrile response influenced by the distinct MMR-related febrile seizure variants, and then, given fever, seizure response influenced by the general febrile seizure variants. A genetic study of children with detailed information about febrile response after MMR vaccination would be needed to reveal if the *IFI44L* and *CD46* variants are associated with specific fever patterns also in individuals who are not susceptible to febrile seizures. Other future investigations are required to identify the precise identity of causal variants at the loci and to determine whether the variants are associated with response to other vaccines or to live virus

infections. Eventually such knowledge may translate into improved vaccine design or personalized vaccination strategies.

Concerning febrile seizures in general, *SCN1A* and *SCN2A* are strong functional candidates at the two independent 2q24.3 loci, since variants in these genes have been linked to a range of epilepsy syndromes, some involving febrile seizures^{5, 6}. Some observations are worth noting. First, variants affecting *SCN2A* function are likely to show age-dependent changes in effect, since Na_v1.2 channels are expressed early in development at the axon initial segment of principal neurons, but are gradually replaced by Na_v1.6 channels during maturation. This has been suggested as a possible explanation for the age-dependent remission of seizures in BFNIS²⁵, and might also play a role in the spontaneous remission of febrile seizures around 6 years of age, if a causal link with *SCN2A* function underlies the febrile seizure association seen in our data. Second, given the predominant expression of Na_v1.1 and Na_v1.2 channels in the axon initial segment of inhibitory interneurons and excitatory pyramidal neurons, respectively, it is conceivable that the *SCN1A* variants affect risk of febrile seizures through decreased activity of the inhibitory circuitry, whereas the *SCN2A* variants act directly by increasing the activity of excitatory neurons. Third, rare *SCN1A* missense mutations are commonly found in DS and GEFS+, two epilepsy syndromes that include febrile seizures as part of the clinical presentation. Mice that are heterozygous for *SCN1A* loss-of-function mutations show a severe phenotype resembling DS^{29, 40}, whereas mice heterozygous for GEFS+ *SCN1A* missense mutations only have partial loss of function and show a much less severe phenotype^{40, 41}. In line with this pattern, we expect future investigations to uncover more subtle effects of the *SCN1A* variants identified here on febrile seizure susceptibility, e.g., involving decreased gene expression or altered regulation of alternative splicing.

The 12q21.33 association indicates that revived research into the role of magnesium deficiency in seizure susceptibility is warranted. In clinical practice, magnesium sulphate has long been used as an effective treatment for the seizures of neonatal tetany⁴² and eclampsia⁴³, and oral magnesium supplementation has been suggested as an adjunct therapy in patients with drug resistant epileptic seizures^{44, 45}. We note that other previously reported magnesium-related loci were not associated with febrile seizures. However, these findings were based on serum concentrations measured in adult participants³⁴, and different loci may regulate different aspects of magnesium metabolism, such as tissue-specific bioavailability, over a lifetime.

The implication of *TMEM16C* variants in general febrile seizure susceptibility opens novel avenues for future research in the field of seizure disorders. Compared to typical GWAS findings in other complex diseases, the odds ratio estimate of 2.09 is unusually high, which together with the supportive electrophysiological results underline the importance of *TMEM16C* as a target for further inquiry. In nociceptive dorsal root ganglion neurons *TMEM16C* acts indirectly by modulating the properties of the sodium activated potassium (K_{Na}) channel *KCNT1* (*SLACK*)³³, but it is unclear whether this is also the case in central neurons, e.g., hippocampal and hypothalamic neurons. Rare *KCNT1* mutations have been reported in two early onset epileptic disorders^{46, 47}, and it will be interesting to determine if the mechanism underlying the association with febrile seizures reported here involves altered cellular excitability through interaction between *TMEM16C* and *KCNT1*.

Given the occurrence of febrile seizures in several epilepsy syndromes, one might speculate whether our association findings for general febrile seizures could be driven by the presence of infants who would later develop epilepsy, e.g., GEFS+ or DS. We consider this scenario highly unlikely since only a small fraction of febrile seizure cases is expected to later develop epilepsy⁷. Thus, an epilepsy variant would need to have an extremely large effect in this set and to be in strong LD with the top SNP at one of the loci for general febrile seizures in order to drive the association. However, among common SNPs at the four loci, the effect size for the only previously reported genome-wide significant epilepsy related SNP, rs7587026, was modest (OR = 1.42)²⁷, and it is implausible that rare large-effect variants in *SCN1A* and *SCN2A* known to cause familial epilepsies can explain the associations with the common SNPs (risk allele frequencies > 0.4) reported here⁴⁸. Furthermore, we found that results did not change when excluding febrile seizure cases who later developed epilepsy (Supplementary Table 5) and that three out of four loci replicated when using an auxiliary set of febrile seizure cases with more than 25 years of follow-up without any records of epilepsy (Supplementary Table 4) with the association signal for rs376995 at the last locus being consistent with the replication stage result in the main analysis (Table 1).

Our study was restricted to individuals of Danish descent, and further studies are needed to examine effects of the identified variants in populations of different ancestry. Several of the 6 SNPs in Table 1 show substantial differences in allele frequency, particularly between East Asian and other populations (Supplementary Fig. 8). The incidence of febrile seizures varies considerably in different populations across the world. In Japan, 6–9% of children experience febrile seizures compared to 2–5% in children of European descent^{3, 49}, and genetic studies in East Asian or other populations might reveal different febrile seizure loci. Further studies are also required to identify the functionally relevant variants at each locus and examine their effects in thoroughly characterized febrile seizure samples across the entire phenotypic spectrum; from isolated febrile seizures (simple or complex) to febrile seizures occurring in specific epilepsy syndromes, such as GEFS+ or DS.

In conclusion, using detailed health register information on vaccinations and febrile seizure episodes, we identified common variants at two loci associated with febrile seizures as an adverse event following MMR vaccination. From a public health perspective, it is essential to study the underlying causes of any serious adverse event of the MMR vaccine, a preventive pharmaceutical product given to millions of children each year, and our findings provide important leads for further research in the fields of immunogenetics and vaccinology. Concomitantly, we identified four loci associated with febrile seizures in general, which together with supporting evidence from electrophysiological experiments underline the importance of altered ion channel function in this common childhood disorder. Further functional studies will illuminate the biological mechanisms behind the associations reported here and might also provide more general insights into mechanisms of epileptogenesis and neuronal hyperexcitability.

ONLINE METHODS

Subjects

The cases for both the discovery and replication stages were identified from the Danish National Patient Register, which includes individual-level information from all hospitals in Denmark including physician-assigned diagnoses and dates of hospital contact⁵⁰. The register includes information on all inpatient admissions since 1977 and all emergency and outpatient hospital contacts since 1995 with diagnostic information coded according to the International Classification of Diseases (ICD, version 8 through 1993 and version 10 from 1994). The positive predictive value of a diagnosis of febrile seizures (ICD-8 and ICD-10) recorded in the register is 93%⁵¹. Information on other medical conditions was similarly obtained from the Danish National Patient Register. Data on gestational age at birth were derived from the Danish Medical Birth Register, which records detailed information on all births in the country⁵². Information on vaccination status and date of vaccination was obtained from the Childhood Vaccination Database at Statens Serum Institut⁵³. Two brands of MMR vaccine have been in use in Denmark through the period during which cases were recruited to the study. MMR II (Sanofi Pasteur MSD, Lyon, France [in the United States: Merck&Co, Whitehouse Station, NJ]) was used through October 17, 2008; this contains the Enders' Edmonston measles strain, the Jeryl Lynn mumps strain, and the Wistar RA27/3 rubella strain. From October 18, 2008, Priorix (GlaxoSmithKline Biologicals, Rixensart, Belgium) has been used; this contains the Schwarz measles strain, the Jeryl Lynn mumps strain, and the Wistar RA27/3 rubella strain. Varicella immunization is not included in the national vaccination program in Denmark. De-identified information was linked between these sources of data, which all have nationwide coverage, through the use of unique personal identifiers.

Cases for the discovery stage were identified from a background population of children born in Denmark between January 1, 1991, and December 31, 2008, with follow-up for an index event of febrile seizures between January 1, 1992, and January 1, 2010. Following identification of febrile seizure cases associated with MMR vaccination, cases of febrile seizures with no association to MMR vaccination were matched according to calendar year of index event. Cases for the replication stage were identified from a background population of children born in Denmark between January 1, 1991, and September 30, 2011, with follow-up for an index event of febrile seizures between January 1, 1992, and September 30, 2012. ICD-8 code 78021 and ICD-10 code R560 were used for case identification. A vaccine-associated case was defined as a case of febrile seizures that occurred in a risk window of 9 to 14 days following the date of MMR vaccination¹. A febrile seizures case with no association to vaccination was defined as a case that occurred 6 weeks or more after vaccination or in an infant with no vaccine exposure (the risk of febrile seizures increases transiently after MMR vaccination and is back to baseline risk by 4 weeks following vaccination^{1, 2}; our definition of cases with no association to vaccination was thus conservative with regard to the time window after vaccination). All cases were required to be between 1 and 2 years of age at the index date of the febrile seizure event, and were allowed to have experienced additional febrile seizure events either before 1 year of age or after the index event. Follow-up information from the Danish National Patient Register was

available until 11 January 2014. At the end of the follow-up period, the febrile seizure cases were between 5.1 and 23.0 years old (median 15.1 years) in the discovery stage and between 2.6 and 23.0 years old (median 10.0 years) in the replication stage. As a sensitivity analysis, we conducted association testing excluding all febrile seizure cases who had an epilepsy or non-febrile seizure diagnosis code during follow-up. Furthermore, an independent set of febrile seizure cases with 25 or more years of follow-up without any epilepsy diagnosis were included in an additional replication stage analysis.

Population controls ($n = 4,118$) for the discovery stage were selected from individuals with GWAS data from various Illumina Omni Arrays generated in other research projects at Statens Serum Institut, excluding individuals with febrile seizures or epilepsy diagnosis codes in the Danish National Patient Register. Controls for the replication stage were randomly selected among children from the Danish National Birth Cohort⁵⁴, who had participated in all surveys including the 11 year follow-up investigation, and who did not have any febrile seizure or epilepsy diagnosis code. Sample characteristics and inclusion criteria for cases and controls are shown in Supplementary Table 1.

To ensure a high degree of genetic homogeneity in the genotyped sample, we obtained birthplace information from the Civil Registration System⁵⁵, and only included subjects who were born in Denmark and whose parents and grandparents were not born outside of northwestern Europe. The study was approved by the Scientific Ethics Committee for the Capital City Region (Copenhagen) and the Danish Data Protection Agency. The Scientific Ethics Committee also granted exemption from obtaining informed consent from participants (H-3-2010-003) since the study was based on biobank material.

Sampling, Amplification and Genotyping

All samples were drawn from the Danish Newborn Screening Biobank and the Danish National Birth Cohort biobank, both of which are part of the Danish National Biobank. All cases and controls were sampled using two 3mm punches from dried blood spot samples. Genomic DNA was extracted using the Extract-N-Amp kit (Sigma-Aldrich, St. Louis, MO, USA) and then whole-genome amplified in triplicate using the Repli-g kit (Qiagen, Hilden, Germany) at Statens Serum Institut as previously described⁵⁶. All 6,117 samples in the discovery stage of the GWAS were genotyped with Illumina Omni Bead Arrays and Genome Studio software; febrile seizure cases ($n = 1,999$) were genotyped using the HumanOmniExpressExome-8 v1.1 array; controls were genotyped using the HumanOmniExpressExome-8 v1.1 array ($n = 1,931$), the HumanOmniExpress-12v1_H array ($n = 1,173$), or the HumanOmni1-Quad v1.0 ($n = 1,014$). For the replication stage, we sampled 408 cases with febrile seizures following MMR vaccination, 1,035 febrile seizure cases unrelated to vaccination, 1,647 controls and 515 febrile seizure cases with 25 years of follow-up without any epilepsy diagnosis. Genomic DNA was extracted from punches of dried blood spot samples and amplified using the same protocol as in the discovery stage. Genotyping for the selected replication stage SNPs was performed using competitive allele-specific PCR (KASP) chemistry (LGC Genomics, Hoddesdon, UK).

Data cleaning and Imputation

The data cleaning process was initiated by aligning all genotypes to the forward strand and restricting the data to the 615,786 SNPs that were available on all three different Omni arrays in the study. Next, we excluded individuals that (i) had more than 4% missing genotypes, (ii) had an autosomal heterozygosity rate deviating more than 2.5 standard deviations from the mean, (iii) had discordant sex information, or (iv) were more than 6 standard deviations away from the mean of any of the first 5 principal components in a principal component analysis. We then excluded SNPs based on a missing rate >2%, minor allele frequency <0.01, and deviations from Hardy-Weinberg Equilibrium ($P < 10^{-6}$). Finally, we excluded SNPs that showed differential missingness between arrays, differences in allele frequencies between arrays, or differences in allele frequencies between male and female subjects. The remaining 548,642 SNPs were used for imputation. We used a two-step procedure to impute unobserved genotypes using phased haplotypes from the integrated Phase I release of the 1000 Genomes Project⁵⁷. In a first pre-phasing step, we used SHAPEIT⁵⁸ to estimate haplotypes for our study samples. In a second step, we imputed missing alleles for additional SNPs directly onto these phased haplotypes using IMPUTE2⁵⁹. We chose imputed SNPs or insertion/deletions (indels) with minor allele frequencies (MAFs) of >1% and SNPTEST⁶⁰ info value of >0.8 for further analyses. Depending on the analysis, this yielded 8,129,553 (febrile seizures overall versus controls), 8,129,524 (MMR-related febrile seizures versus controls), 8,129,384 (MMR-unrelated febrile seizures versus controls), or 8,129,288 (MMR-related febrile seizures versus MMR-unrelated febrile seizures) imputed genetic variants. To further assess imputation accuracy of the six genome-wide significant SNPs in Table 1, these were genotyped in a subset of 762 discovery stage samples (181 MMR-related febrile seizure cases, 202 MMR-unrelated febrile seizure cases, 379 controls) using KASP assays. The concordance between observed allele counts and imputed allele dosages was high (all six SNPs had $r^2 > 0.96$) indicating that imputation was accurate for these SNPs.

Association Analysis

We used logistic regression to test for differences in allele dosages between cases and controls under an additive genetic model. We carried out combined analysis of the discovery and replication stage data using the inverse variance method applying genomic control⁶¹ to the discovery stage results. Genomic inflation factors were 1.01, 1.00, 1.02, and 1.03 for the four scans (MMR-related febrile seizures versus controls; MMR-related febrile seizures versus MMR-unrelated febrile seizures; MMR-unrelated febrile seizures versus controls; and febrile seizures overall versus controls), respectively, indicating minimal population stratification. In line with this, association results were essentially unchanged when adjusting for the first five principal components from our principal components analysis. We therefore report results where test statistics were scaled by genomic control using the genomic inflation factors, but where no further adjustment was made based on principal components. We estimated heterogeneity between discovery and replication results using the I^2 statistic⁶². In order to explore possible allelic heterogeneity, we conducted analyses conditioning on the top SNP at each of the selected loci. Using the combined discovery and replication data, we tested for interaction effects between the two loci associated with febrile

seizures following MMR vaccination and also between the four loci associated with febrile seizures in general by including risk allele count at each locus in a logistic regression model together with pairwise interaction terms. We evaluated the combined impact of the associated loci by constructing genetic risk scores for all individuals in the discovery and replication samples. For each SNP, a weight ($\log(\text{OR})$) was multiplied by the number (or dosage) of risk alleles. The genetic risk scores were then calculated by summation over the two SNPs associated with MMR-related febrile seizures, or by summation over the four SNPs associated with febrile seizures overall. We used the weighted risk scores in logistic regression analyses. The association analyses were conducted using SNPTEST, METAL⁶³, and R (<http://www.r-project.org/>) software.

Power analysis

For each of the four scans, we estimated the power of the discovery sample at a significance threshold of $P < 1 \times 10^{-6}$ (Supplementary Table 8), since this threshold was used to select SNPs for replication genotyping (Supplementary Fig. 3). Power estimates are presented at representative and relevant odds ratios (ORs) (OR = 1.25, OR = 1.4, OR = 1.5 and OR = 2.0) and risk allele frequencies (0.05, 0.20, 0.30, 0.40 and 0.70). The power analyses were performed using the Genetic Power Calculator⁶⁴.

Bioinformatics analysis

For each locus with genome-wide significant SNPs, we explored possible functional effects of the associations by considering all genotyped or imputed variants with $P < 1 \times 10^{-5}$ at the locus. We searched the National Human Genome Research Institute (NHGRI) GWAS catalog (www.genome.gov/gwastudies) and the National Center for Biotechnology Information (NCBI) Genotype-Tissue Expression (GTEx) database (<http://www.ncbi.nlm.nih.gov/gtex/GTEX2/gtex.cgi>) for previously reported trait or eQTL associations for these variants using P value thresholds of 5×10^{-8} and 1×10^{-4} , respectively. Furthermore, we searched the blood eQTL browser¹² (<http://genenetwork.nl/bloodeqtlbrowser>) for cis and trans eQTL associations in peripheral blood, and the GEUVADIS data browser¹¹ (<http://www.ebi.ac.uk/Tools/geuvadis-das>) for exon and transcript level eQTL associations in lymphoblastoid cell lines. Ensembl (release 74; <http://www.ensembl.org>) IDs were used for annotation of transcripts. MutationTaster⁶⁵ and PolyPhen-2⁶⁶ were used to predict deleteriousness of missense mutations.

Cell-based assays

Assays to assess the impact of ectopic ISG expression on virus infection have been described previously^{14, 67}. Briefly, SCRPSY lentiviral vectors (provided by P. Bieniasz) were used to express the IFI44L variants or an empty cassette as control. Lentiviral-transduced *STAT1*^{-/-} fibroblasts (originally from the lab of J.-L. Casanova) were infected with 1.0 MOI Edmonston strain measles-GFP (provided by R. Cattaneo)⁶⁸. Cells were harvested 24 h post-infection and the percentage of infected cells was quantified by flow cytometry. Tests for mycoplasma contamination of the cells were conducted on multiple occasions (before and after completion of the experiments) and were all negative.

Brain slice preparation

Tmem16C knockout rats and wild-type litter mates were bred at University of California, San Francisco (UCSF) as reported previously³³, and used for whole-cell patch-clamp recordings; they were maintained under a 12:12 hour light/dark schedule, and they consumed food and water *ad libitum*. All protocols were approved by the IACUC at UCSF, and are fully compliant with NIH guidelines for humane treatment of animals.

Postnatal day 10–14 rats were anesthetized with isoflurane and decapitated. Brains were removed and submerged in ice-cold sucrose slicing solution (in mM): 2.5 KCl, 10 MgSO₄·7H₂O, 0.5 CaCl₂·2H₂O, 1.25 NaH₂PO₄·H₂O, 26 NaHCO₃, 11 glucose, 234 sucrose, pH 7.2–7.4, saturated with 95% O₂/5% CO₂. 350- μ m-thick coronal slices containing anterior hypothalamic nucleus (AHN) or hippocampal CA1 neurons were prepared using Leica VT1000s vibratome and transferred to a holding chamber containing artificial cerebral spinal fluid (ACSF, in mM): 126 NaCl, 2.5 KCl, 2 MgCl₂, 2 CaCl₂, 1.25 NaH₂PO₄, 26 NaHCO₃, 10 glucose, pH 7.2–7.4 saturated with 95% O₂/5% CO₂ at 37°C for 20 min for the slices to recover from the treatment in the ice-cold solution, and further incubated for at least 1 hour at room temperature before recording at various temperatures.

Electrophysiology

Whole-cell patch electrodes had pipette tip resistances of 4–6 M Ω , and were filled with a solution containing (in mM): 122 K-gluconate, 13 KCl, 0.07 CaCl₂, 1.0 MgCl₂, 0.1 EGTA, 10.0 HEPES, 4.0 Na-ATP, 0.4 Na-GTP, pH 7.3, and osmolality 290–300 mOsm/L. Recordings were performed using a Multiclamp 700B amplifier (Molecular Devices, Sunnyvale, CA). Signals were sampled at 10 kHz, low-pass filtered at 10 kHz using a Digidata 1440 digitizer, and stored on computer for subsequent analyses using pClamp software (Molecular Devices, Sunnyvale, CA). Liquid junction potential was corrected in reported results. In patch-clamp recordings, access resistance (<15 M Ω) was continuously monitored throughout each experiment. If the fluctuation deviated more than 20% from the baseline values, the cell was regarded as unhealthy or unsuccessful patch, and the recording was excluded. The investigators were blinded to the host animal's genotype while performing electrophysiological recordings.

Whole-cell patch recording was initiated by breaking into the cell under current-clamp mode, followed with current-steps (duration 400 ms) from –100 pA to 120 pA, with a 20 pA increment; the basic membrane properties (at 36.5°C for AHN neurons; at room temperature, 36.5°C, and 40°C for hippocampal neurons) including resting membrane potential (V_m), input resistance (R_{in}), membrane capacitance (C_m) and time constant (τ) were obtained. Specifically, the V_m was obtained directly at holding current 0 pA; R_{in} was determined from the slope of the current-voltage (I–V) relationship at 0 pA holding current by linear regression; τ was determined from the voltage response to –20 pA current injection by exponential regression; C_m was calculated as τ/R_{in} .

In hippocampal recordings, we compared the frequency of action potentials elicited by injection of various amounts of current into wild-type and *Tmem16C* knockout neurons, at room temperature, 36.5°C and 40°C. In hypothalamic recordings, firing rate was monitored

following the shifts of bath temperature between 33°C and 40°C. The bath temperature was controlled using an inline heater (Warner, SC-20). Spontaneous action potentials (SAPs) were counted at the corresponding temperature, and neurons were classified based on their responses: temperature-insensitive neurons have the same frequency of SAP at 33°C, 36.5°C or 40°C; heat-sensitive neurons exhibit a decrease of firing rate during cooling and an increase of SAP firing rate during warming; cold-sensitive neurons show the opposite temperature dependence; silent neurons do not discharge SAPs during the duration of recording.

Fisher's exact test, Student's t-test, or two-way ANOVA followed by Tukey's post-hoc honestly significant difference (HSD) test was used to compare the recordings of wild-type with Tmem16C knockout neurons from the hippocampus and the hypothalamus. All comparisons were based on a sample size of $n > 5$ in line with common practice in single cell electrophysiological recordings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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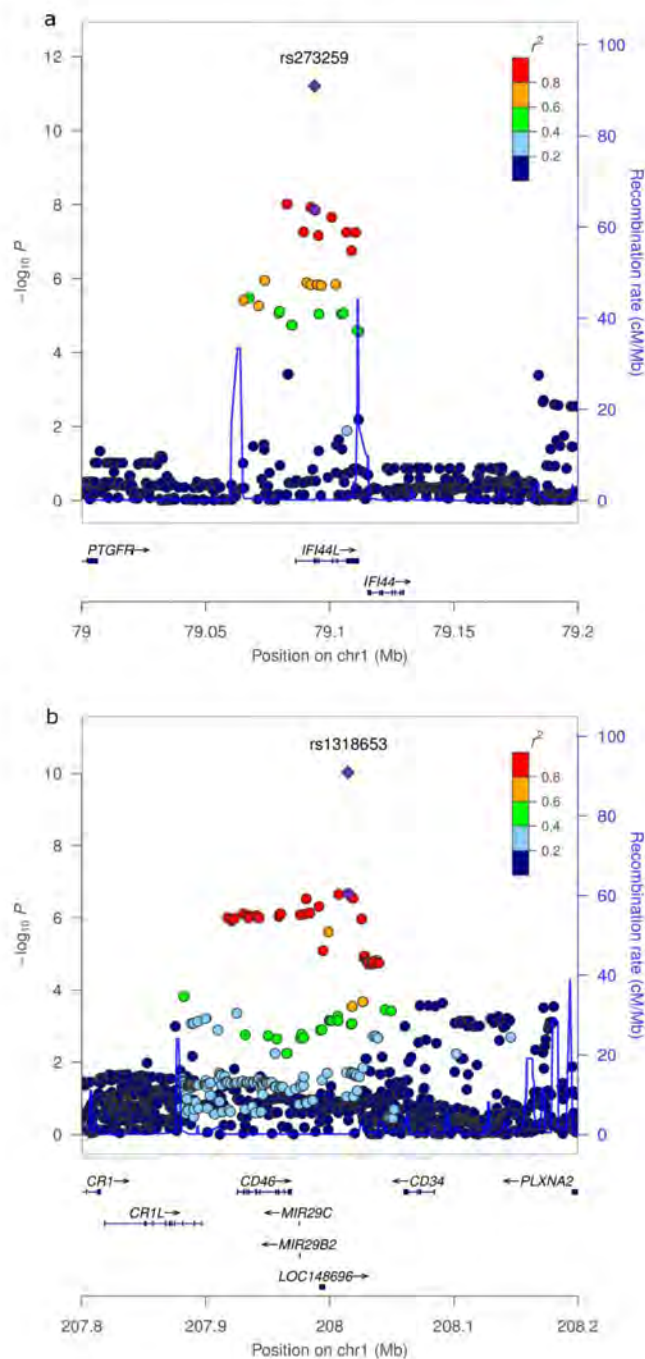


Figure 1. Discovery stage results from the MMR-related febrile seizures versus controls scan. **(a, b)** Regional association plots for the **(a)** 1p31.1 locus, and **(b)** 1q32.2 locus. SNPs are plotted by chromosomal location (x-axis) and disease association ($-\log_{10} P$ value; left y-axis). The colors reflect linkage disequilibrium of each SNP with the top SNP at the locus, and recombination rates (from HapMap; right y-axis) are shown to reflect local linkage disequilibrium structure. The P value for the top SNP in the combined analysis is

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represented by a purple diamond, and that from the discovery stage analysis by a purple circle.

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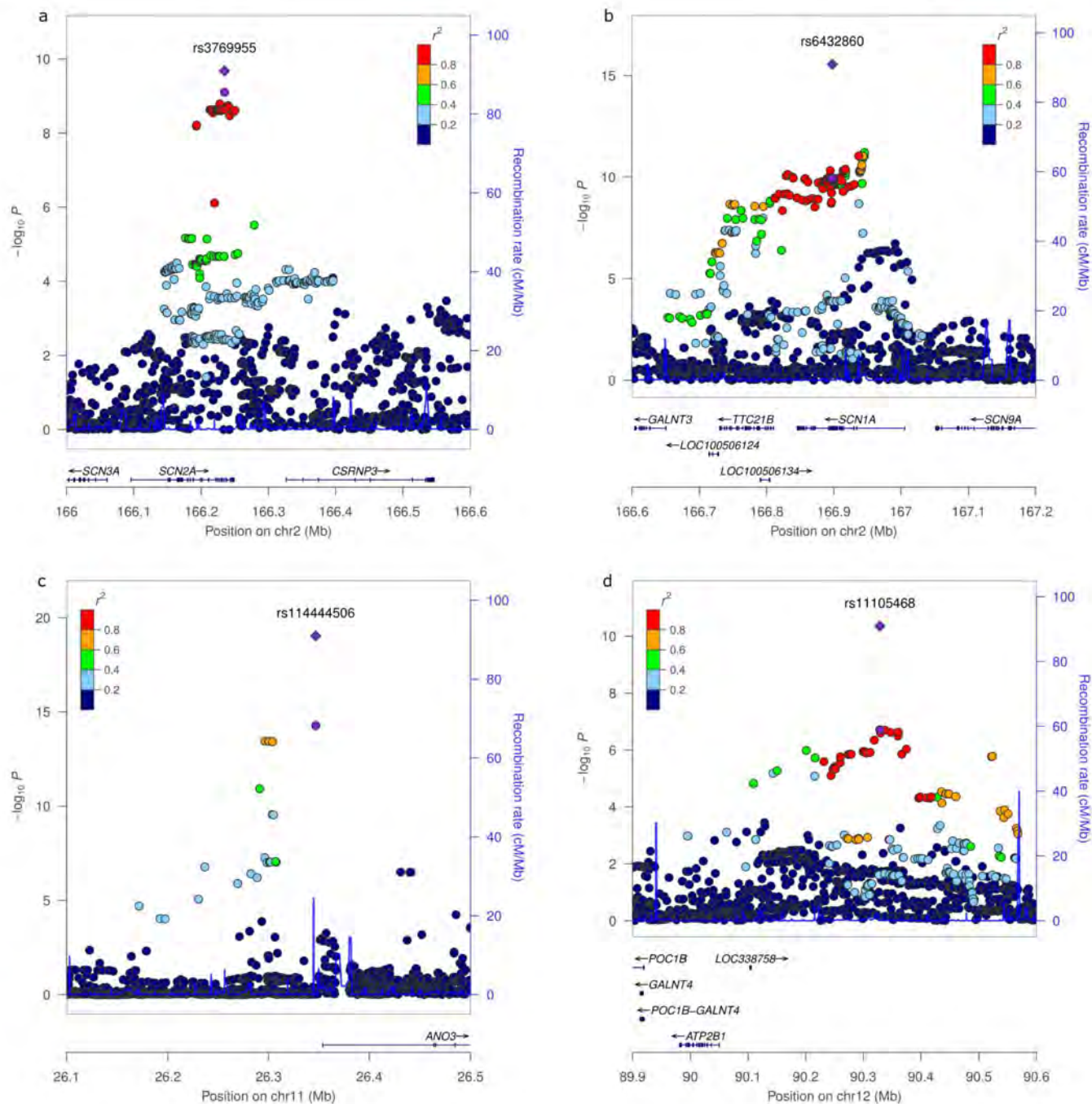
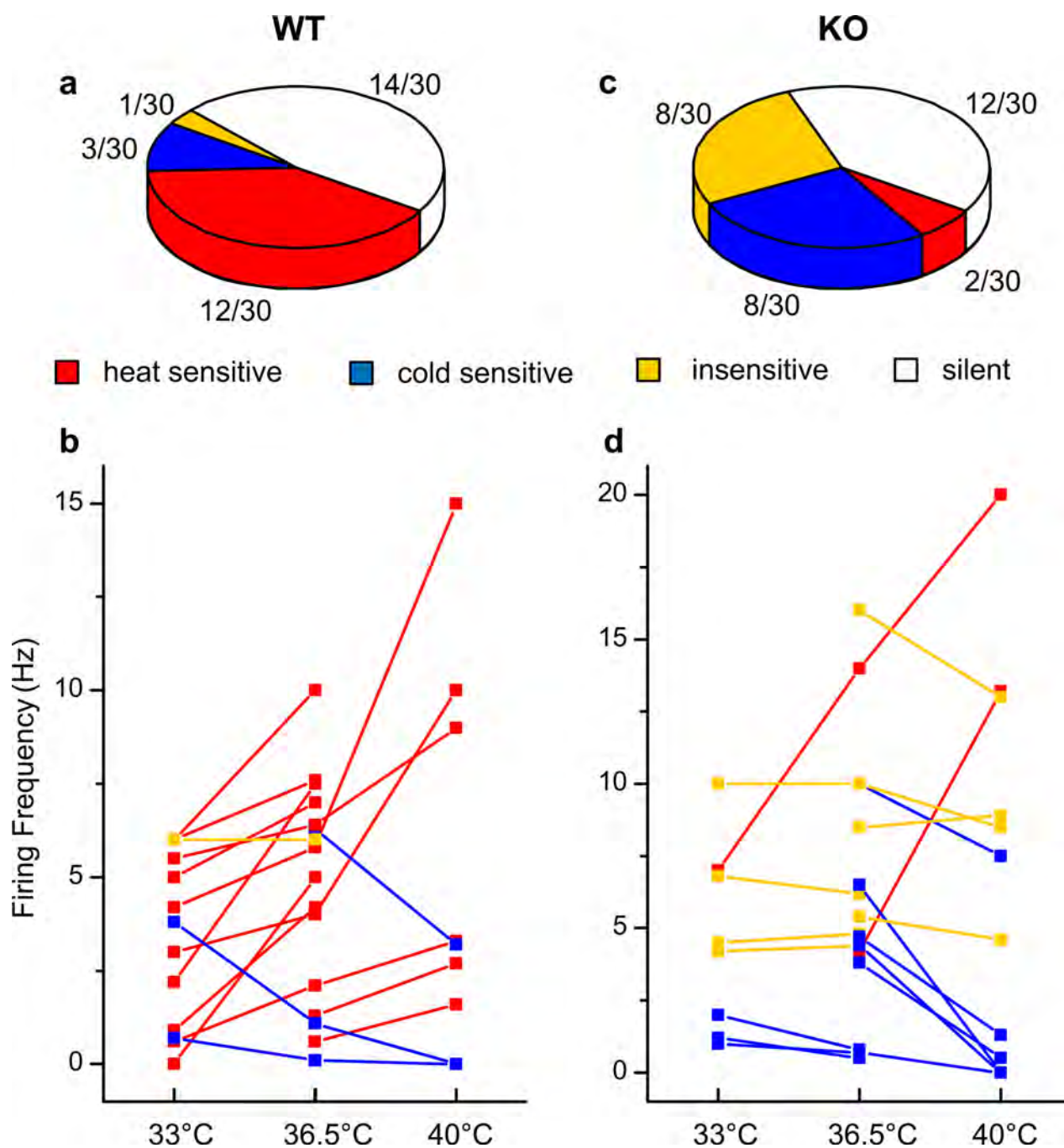


Figure 2. Discovery stage results from the febrile seizures overall versus controls scan. (a–d) Regional association plots for the (a) 2q24.3 (*SCN2A*) locus, (b) 2q24.3 (*SCN1A*) locus, (c) 11p14.2 locus, and (d) 12q21.33 locus. SNPs position (x-axis) and disease association ($-\log_{10} P$ value; left y-axis) are shown, and the colors reflect linkage disequilibrium of each SNP with the top SNP at the locus. Recombination rates are from HapMap (right y-axis). The P value for the top SNP in the combined analysis is represented by a purple diamond, and that from the discovery stage analysis by a purple circle.

**Figure 3.**

TMEM16C is involved in hypothalamic neurons' temperature response. Neurons in the anterior hypothalamic nucleus (AHN) were classified based on their temperature responses as heat-sensitive (red), cold-sensitive (blue), temperature-insensitive (light orange), or silent (white). Proportion of each type of neurons in AHN from (a) wild-type (WT) or (c) knockout (KO) rats. Firing frequencies of each individual neurons from (b) WT or (d) KO rats recorded at 33°C, 36.5°C or 40°C. A lower proportion of heat-sensitive neurons were

detected in *Tmem16C* knockout slices ($n = 30$ recorded neurons), compared with wild-type ($n = 30$; $P = 0.005$, Fisher's exact test).

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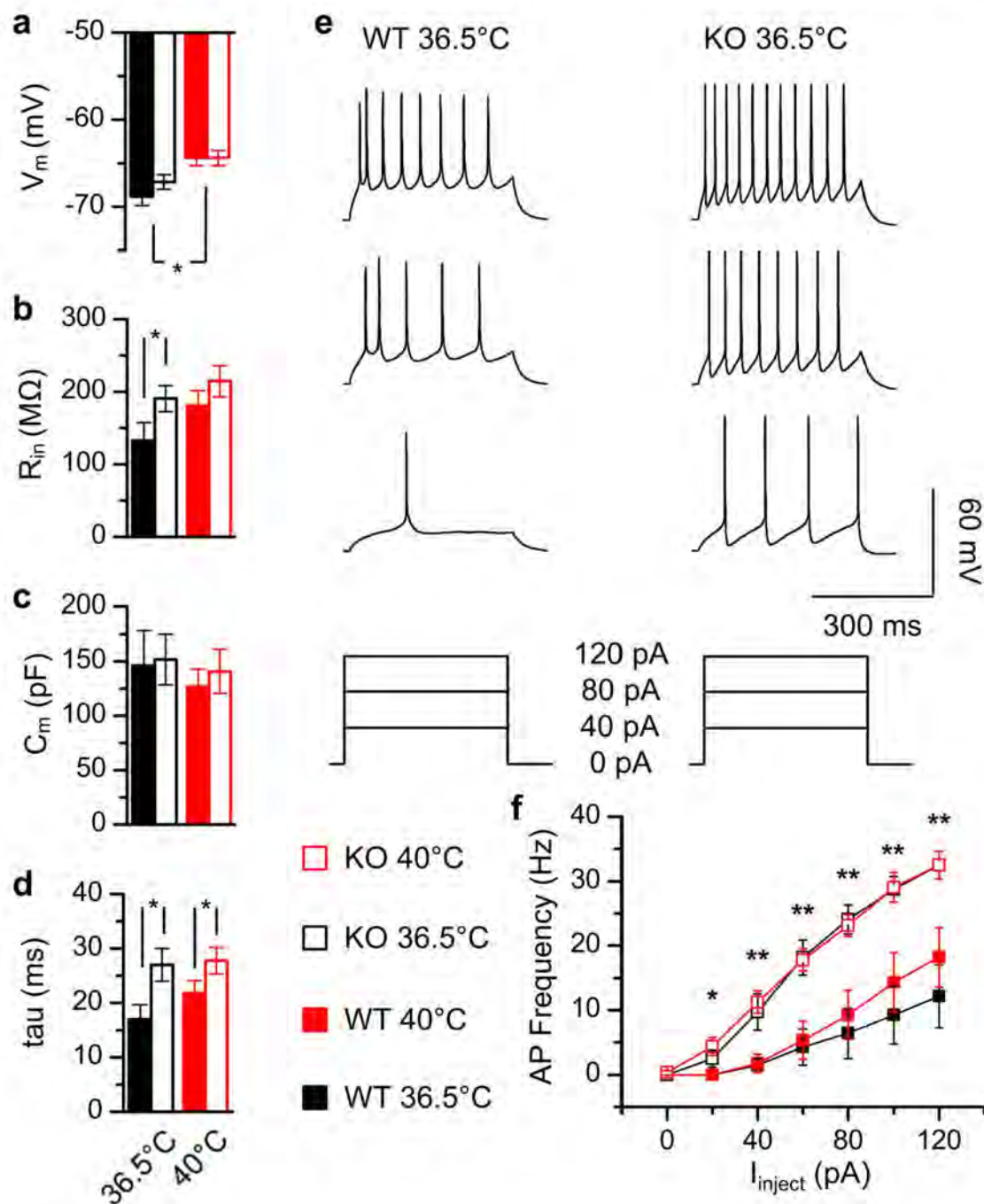


Figure 4. Hippocampal CA1 pyramidal neurons exhibit hyperexcitability in the absence of *TMEM16C*. (a–d) Basic membrane properties (*, $P < 0.05$, two-way ANOVA followed by HSD test), namely (a) resting membrane potential (V_m), (b) input resistance (R_{in}), (c) membrane capacitance (C_m) and (d) time constant (τ) at 36.5°C and 40°C, for wild-type (WT) vs., *Tmem16C* knockout (KO) neurons ($n = 7-8$). (e) Sample traces of neuronal responses to 40, 80, and 120 pA current injections in wild-type vs. knockout CA1 pyramidal neurons at 36.5°C. (f) Current-steps elicit more action potentials in knockout neurons

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compared to wild-type controls ($n = 7-8$; **, $P < 0.01$, *, $P < 0.05$, WT vs. KO, two-way ANOVA). Error bars indicate s.e.m.

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Table 1

Discovery, replication and combined results for six loci associated with febrile seizures following MMR vaccination and overall. Results with $P < 1.25 \times 10^{-8}$ are marked in bold. “MMR+” represents MMR-related febrile seizure cases and “MMR-” represents MMR-unrelated febrile seizure cases. “Ctrls” in the MMR-related vs. unrelated febrile seizure analyses are febrile seizure cases unrelated to MMR vaccination. Ctrls, controls. CI, confidence interval. FS, febrile seizures., I^2 , heterogeneity estimate., P_{het} , P value from Cochran Q test of heterogeneity.

Chromosome Position (bp)	SNP (effect/alternative allele)	Analysis	Discovery (MMR-related FS, $n = 929$, MMR-unrelated FS, $n = 1,070$, FS overall, $n = 1,999$, Controls, $n = 4,118$)				Replication (MMR-related FS, $n = 405$ to 408 , MMR-unrelated FS, $n = 1,030$ to $1,034$, FS overall, $n = 1,435$ to $1,442$, Controls, $n = 1,625$ to $1,645$)				Combined (MMR-related FS, $n = 1,334$ to $1,337$, MMR-unrelated FS, $n = 2,100$ to $2,104$, FS overall, $n = 3,434$ to $3,441$, Controls, $n = 5,743$ to $5,863$)				
			Effect Allele frequency	Odds Ratio		P	Effect Allele Frequency	Odds Ratio		P	Odds Ratio	P	I^2	P_{het}	
<i>Loci for MMR-related FS</i>															
1	79093818	MMR+ vs ctrls MMR+ vs MMR- MMR- vs ctrls All FS vs ctrls	A/G	0.767	0.702	1.40 (1.25–1.57)	1.4×10^{-8}	0.754	0.683	1.42 (1.19–1.69)	9.2×10^{-5}	1.41 (1.28–1.55)	5.9×10^{-12}	0	0.91
				0.767	0.694	1.46 (1.26–1.69)	2.0×10^{-7}	0.754	0.692	1.36 (1.13–1.64)	0.00096	1.42 (1.27–1.59)	1.2×10^{-9}	0	0.57
				0.694	0.702	0.97 (0.87–1.07)	0.52	0.692	0.683	1.04 (0.92–1.17)	0.53	1.00 (0.92–1.08)	0.95	0	0.36
				0.728	0.702	1.14 (1.05–1.24)	0.0027	0.709	0.683	1.13 (1.01–1.26)	0.028	1.14 (1.06–1.21)	0.0002	0	0.91
1	208014922	MMR+ vs ctrls MMR+ vs MMR- MMR- vs ctrls All FS vs ctrls	T/C	0.828	0.774	1.41 (1.24–1.60)	2.1×10^{-7}	0.831	0.767	1.49 (1.22–1.82)	8.8×10^{-5}	1.43 (1.28–1.59)	9.6×10^{-11}	0	0.64
				0.828	0.771	1.44 (1.23–1.68)	5.9×10^{-6}	0.831	0.761	1.55 (1.25–1.91)	4.1×10^{-5}	1.48 (1.30–1.67)	1.6×10^{-9}	0	0.59
				0.771	0.774	0.98 (0.87–1.10)	0.74	0.761	0.767	0.96 (0.85–1.10)	0.58	0.97 (0.89–1.06)	0.54	0	0.84
				0.797	0.774	1.15 (1.05–1.26)	0.0037	0.781	0.767	1.08 (0.96–1.22)	0.22	1.12 (1.04–1.21)	0.0023	0	0.41
<i>Loci for FS overall</i>															
2	166234632	MMR+ vs ctrls MMR+ vs MMR-	(T/C)	0.455	0.4	1.26 (1.13–1.39)	1.4×10^{-5}	0.451	0.417	1.15 (0.99–1.34)	0.076	1.22 (1.12–1.33)	4.2×10^{-6}	0	0.35
				0.455	0.462	0.97 (0.86–1.10)	0.64	0.451	0.444	1.03 (0.87–1.21)	0.74	0.99 (0.90–1.09)	0.87	0	0.59

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Chromosome Position (bp)	SNP (effect/alternative allele)	Discovery (MMR-related FS, <i>n</i> = 929, MMR-unrelated FS, <i>n</i> = 1,070, FS overall, <i>n</i> = 1,999, Controls, <i>n</i> = 4,118)				Replication (MMR-related FS, <i>n</i> = 405 to 408, MMR-unrelated FS, <i>n</i> = 1,030 to 1,034, FS overall, <i>n</i> = 1,435 to 1,442, Controls, <i>n</i> = 1,625 to 1,645)				Combined (MMR-related FS, <i>n</i> = 1,334 to 1,337, MMR-unrelated FS, <i>n</i> = 2,100 to 2,104, FS overall, <i>n</i> = 3,434 to 3,441, Controls, <i>n</i> = 5,743 to 5,863)			
		Effect Allele frequency		Odds Ratio	<i>P</i>	Effect Allele Frequency		Odds Ratio	<i>P</i>	Odds Ratio		<i>I</i> ²	<i>P</i> _{het}
		Cases	Ctrls	(95% CI)		Cases	Ctrls	(95% CI)		(95% CI)	<i>P</i>		
2 166897864 rs6432860 (G/A)	MMR- vs ctrls	0.462	0.4	1.30 (1.17–1.43)	2.1×10^{-7}	0.444	0.417	1.12 (1.00–1.25)	0.047	1.22 (1.13–1.31)	1.9×10^{-7}	73	0.05
	All FS vs ctrls	0.459	0.4	1.28 (1.18–1.38)	7.9×10^{-10}	0.446	0.417	1.13 (1.02–1.25)	0.02	1.22 (1.15–1.30)	3.1×10^{-10}	72	0.06
	MMR+ vs ctrls	0.777	0.704	1.48 (1.31–1.66)	1.0×10^{-10}	0.754	0.709	1.26 (1.06–1.50)	0.01	1.41 (1.27–1.55)	1.0×10^{-11}	53	0.14
	MMR+ vs MMR-	0.777	0.744	1.20 (1.04–1.39)	0.014	0.754	0.771	0.91 (0.75–1.10)	0.33	1.08 (0.96–1.22)	0.18	80	0.02
	MMR- vs ctrls	0.744	0.704	1.22 (1.10–1.36)	0.00024	0.771	0.709	1.38 (1.22–1.57)	5.6×10^{-7}	1.29 (1.19–1.40)	1.7×10^{-9}	52	0.15
	All FS vs ctrls	0.76	0.704	1.33 (1.22–1.45)	1.2×10^{-10}	0.767	0.709	1.35 (1.20–1.51)	3.4×10^{-7}	1.34 (1.25–1.43)	2.2×10^{-16}	0	0.87
11 26346831 rs114444506 (C/T)	MMR+ vs ctrls	0.06	0.028	2.26 (1.76–2.89)	1.1×10^{-10}	0.049	0.028	1.81 (1.24–2.64)	0.002	2.11 (1.72–2.60)	1.5×10^{-12}	0	0.34
	MMR+ vs MMR-	0.06	0.055	1.11 (0.84–1.46)	0.46	0.049	0.054	0.91 (0.63–1.32)	0.61	1.03 (0.83–1.29)	0.77	0	0.4
	MMR- vs ctrls	0.055	0.028	2.07 (1.62–2.64)	5.0×10^{-9}	0.054	0.028	1.99 (1.50–2.64)	1.3×10^{-6}	2.03 (1.69–2.45)	4.8×10^{-14}	0	0.83
	All FS vs ctrls	0.058	0.028	2.18 (1.79–2.64)	5.2×10^{-15}	0.052	0.028	1.94 (1.49–2.52)	6.9×10^{-7}	2.09 (1.79–2.44)	3.7×10^{-20}	0	0.49
12 90328833 rs11105468 (A/T)	MMR+ vs ctrls	0.342	0.292	1.26 (1.13–1.40)	3.2×10^{-5}	0.359	0.296	1.33 (1.14–1.57)	0.0005	1.28 (1.17–1.40)	6.5×10^{-8}	0	0.56
	MMR+ vs MMR-	0.342	0.338	1.02 (0.90–1.16)	0.76	0.359	0.339	1.09 (0.92–1.29)	0.31	1.05 (0.94–1.16)	0.39	0	0.54
	MMR- vs ctrls	0.338	0.292	1.23 (1.11–1.36)	7.6×10^{-5}	0.339	0.296	1.22 (1.08–1.37)	0.0009	1.23 (1.14–1.33)	2.4×10^{-7}	0	0.92
	All FS vs ctrls	0.34	0.292	1.24 (1.15–1.35)	2.0×10^{-7}	0.345	0.296	1.25 (1.12–1.39)	3.9×10^{-5}	1.25 (1.17–1.33)	3.4×10^{-11}	0	0.92

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Exhibit RR

Conflicts of Interest in Vaccine Policy Making
Majority Staff Report
Committee on Government Reform
U.S. House of Representatives
June 15, 2000

Section I

Introduction

In August 1999, the Committee on Government Reform initiated an investigation into Federal vaccine policy. Over the last six months, this investigation has focused on possible conflicts of interest on the part of Federal policy-makers. Committee staff has conducted an extensive review of financial disclosure forms and related documents, and interviewed key officials from the Department of Health and Human Services, including the Food and Drug Administration and the Centers for Disease Control and Prevention.

This staff report focuses on two influential advisory committees utilized by Federal regulators to provide expert advice on vaccine policy:

1. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC); and
2. The CDC's Advisory Committee on Immunizations Practices (ACIP).

The VRBPAC advises the FDA on the licensing of new vaccines, while the ACIP advises the CDC on guidelines to be issued to doctors and the states for the appropriate use of vaccines.

Members of the advisory committees are required to disclose any financial conflicts of interest and recuse themselves from participating in decisions in which they have an interest. The Committee's investigation has determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings. Among the specific problems identified in this staff report:

§ The CDC routinely grants waivers from conflict of interest rules to every member of its advisory committee.

§ CDC Advisory Committee members who are not allowed to vote on certain recommendations due to financial conflicts of interest are allowed to participate in committee deliberations and advocate specific positions.

§ The Chairman of the CDC's advisory committee until very recently owned 600 shares of stock in Merck, a pharmaceutical company with an active vaccine division.

§ Members of the CDC's advisory Committee often fill out incomplete financial disclosure statements, and are not required to provide the missing information by CDC ethics officials.

§ Four out of eight CDC advisory committee members who voted to approve guidelines for the rotavirus vaccine in June 1998 had financial ties to pharmaceutical companies that were developing different versions of the vaccine.

§ 3 out of 5 FDA advisory committee members who voted to approve the rotavirus vaccine in December 1997 had financial ties to pharmaceutical companies that were developing different versions of the vaccine.

A more complete discussion of specific conflict of interest problems identified by Government

Reform Committee staff can be found in Sections 4 and 5 of this report. To provide focus to the discussion, this report examines the deliberations of the two committees on one specific vaccine -- the Rotavirus vaccine. Approved for use by the FDA on August 31, 1998, the Rotavirus vaccine was pulled from the market 13 months later after serious adverse reactions to the vaccine emerged. Financial disclosure forms and waivers granted to committee members who participated in these meetings were analyzed, along with their votes and actions taken during the meetings.

Section II

Laws and Regulations

Laws Governing Advisory Committees

Federal law requires that advisory committees be balanced in terms of points of view of their members and that they conduct their business in public. The law also requires that advisory committee members disclose their financial interests and recuse themselves from matters in which they have an interest. The following is a brief description of the requirements of these laws:

1. Federal Advisory Committee Act (FACA)[i]:

The FACA, signed into law by President Richard Nixon in 1972, regulates advisory committees, task forces and councils established by either the President, the federal agencies or Congress. These increasingly influential advisory bodies have been considered by many to be the A fifth branch of government.[ii] It is important to note, however, that the FACA does not address the conflict of interest of committee members; these are addressed in a separate statute and dealt with by individual agencies in the Code of Federal Regulations.[iii] The FACA's most significant requirements fall into three basic categories:

a.) Scope of Committees: The statute clearly states that the function of advisory committees is to be Advisory only. They provide advice and recommendations that may or not may be adopted. The final determination is to be made by the official or agency involved.[iv]

b.) Requirement of Openness: The second important issue addressed by the FACA is the need for openness in the proceedings of advisory committees. With very few exceptions, all advisory committee meetings are to be open to the public and the materials distributed at the meetings, including working papers, studies agendas, etc..., are to be made available to the public for inspection.[v]

c.) Balanced Representation: Perhaps the most controversial provision of the FACA is the need for a membership that is Afairly balanced in terms of the points of view represented and the functions of the committee.[vi] The statute specifically forbids the committees to be inappropriately influenced by special interests.[vii]

2. Conflicts of Interest Statutes [viii]:

The ethics guidelines for the advisory committees are set by the agencies in accordance with federal statute, specifically 18 U.S.C. "202-209. Under the statute, advisory committee members are considered ASpecial Government Employees (SGEs). SGEs provide temporary services to the U.S. government, not to exceed 130 days a year. As SGEs, advisory committee members must comply with Federal conflict of interest laws. 18 U.S.C. "202-209 broadly prohibits employees, including SGEs, from participating in a decision-making process when they have a personal interest in the matters discussed, absent a waiver from the relevant parties .[ix] The types of waivers found in the statute are:

a.) (b)(1) waivers: The employee may participate when the appointing official determines that the financial interest is not substantial as to be deemed likely to affect the integrity of the services that the Government may expect.[x]

b.) (b)(2) waivers: Employee may participate if the interest is so remote or inconsequential that it

will not have a special or distinct effect on the employee or his employer.[xi]

c.) (b)(3) waivers: specifically applicable to advisory committee members, this waiver will allow them to participate in matters for which he would have been disqualified, if it is determined that the need for the employees services outweigh the potential conflict of interest created by the employees financial interest.[xii] Factors that may be considered include: type of interest, identity of the person, uniqueness of the individuals qualifications, difficulty of locating a similarly qualified individual without a disqualifying interest, the dollar value of the interest- including its value relevant to the members assets, and the extent to which the financial interest will be affected by the actions of the committee.

3. Code of Federal Regulations (CFR) & Office of Government Ethics (OGE):

Since most advisory committee members are considered special government employees, the provisions in 18 U.S.C. "201-219 that address conflicts of interest apply to them. However, the statute only provides broad guidelines, so that it is up to the individual agencies to provide the specific rules governing conflict of interest.[xiii] In the case of the Department of Health and Human Services (DHHS), these regulations can be found at 5 C.F.R. " 2635 and in 5 C.F.R. "2640. Under the DHHS regulations, an advisory committee member may not participate, absent a waiver, in matters in which they have a financial interest. These are divided into the following categories:

a.) Particular matter: includes matters that involve deliberation, decision, or action focused on the interests of specific persons, or a discrete and identifiable class of persons.[xiv]

b.) Particular matter involving specific parties: the code defines this term to include proceedings, applications, requests for determination, contracts, claims, controversies and/or investigations involving specific parties. The term typically involved a specific proceeding affecting the legal rights of the parties, or an isolatable transaction or related set of transactions between identified parties.[xv] This term will generally refer to the particular issue, vaccine and or company that will be directly affected by the advisory committee discussions.

c.) Particular matter of general applicability: the code defines this term as a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties.[xvi] This definition becomes relevant in the discussion of companies that may be indirectly affected by the proceedings of an advisory committee. In this report, the companies under this category will be referred to as affected companies.

d.) A direct and predictable effect on their financial interest: a direct effect on a financial interest is defined as a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.[xvii] According to the CFR, the effect may actually be considered direct even though it does not occur immediately. However, the CFR also specifies that the link will not be direct in instances where the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative.[xviii] On the other hand, predictable is defined in the code as a situation where there is a real possibility that the matter will be affected.

e.) Affected interests: according to the CFR, the disqualifying financial interests include: salary, indebtedness, job offer, or any other similar interests that could be affected by the matter discussed.[xix] It also includes the interests of persons other than the advisory committee members, such as a spouse, children, general partner, place of employment, organizations where the advisory committee member serves as officer, director and/or trustee, and prospective employers.[xx]

f.) Interests in securities: The CFR specifically addresses the potential conflicts that may arise out of interests in securities, such as stock holdings. The guidelines provided for in the CFR include:

(1) De minimis exemption: This exemption applies to publicly-traded or long-term

Federal/municipal securities. The CFR states that persons having holdings in the specific parties involved of \$5,000 or less or holdings in the affected companies of \$25,000 or less will be allowed to participate in the proceedings of the advisory committee. (Exhibit 53) These financial interests are deemed to be of low involvement and do not require a waiver, but a simple disclosure on the forms required by the particular agency or department.

(2) Employment exemption: Under the DFR, SGEs may participate in the advisory committee discussions on matters of general applicability so long as the otherwise disqualifying financial interest arises only from the committee members non-Federal employment or prospective employment and so long as the matter does not have a special or distinct effect on the employee or employer other than as part of a class. In other words, under these circumstances, employees will be granted an automatic waiver.

g.) Teaching, speaking and writing on subject of meeting: SGEs are prohibited from receiving compensation for teaching, speaking, and writing on subjects related to the employees official duties in the advisory committee.[xxi]

The Code also stipulates that an SGE may not participate in matters that are likely to have a direct and predictable effect on the financial interests of ...a person with whom he has a covered relationship, including members of his household, close friends or employer.[xxii] This type of conflict requires that the member disclose the potential conflict and that said conflict be waived by the agency designee.

Section III

The Rotavirus and the Rotashield Vaccine

A. What is Rotavirus?

Rotaviruses cause acute gastroenteritis. Rotavirus gastroenteritis is a self-limiting, mild to severe disease characterized by vomiting, watery diarrhea, and low-grade fever. Infantile diarrhea, winter diarrhea, acute nonbacterial infectious gastroenteritis, and acute viral gastroenteritis are names applied to the infection caused by the most common and widespread "Group A rotavirus."

Person-to-person spread through contaminated hands is probably the most important means by which rotaviruses are transmitted in close communities such as pediatric and geriatric wards, day care centers and family homes. Group A rotavirus is endemic worldwide. It is the leading cause of severe diarrhea among infants and children, and accounts for about half of the cases requiring hospitalization.

It is estimated that over 3 million cases of rotavirus gastroenteritis occur annually in the United States. In temperate areas, it occurs primarily in the winter, but in the tropics it occurs throughout the year.

Group B rotavirus, also called adult diarrhea rotavirus or ADRV, has caused major epidemics of severe diarrhea affecting thousands of persons of all ages in China. Group C rotavirus has been associated with rare and sporadic cases of diarrhea in children in many countries. However, the first outbreaks were reported from Japan and England.

The incubation period ranges from 1-3 days. Symptoms often start with vomiting followed by 4-8 days of diarrhea. Temporary lactose intolerance may occur. Recovery is usually complete. However, severe diarrhea without fluid and electrolyte replacement may result in severe diarrhea and death.

Childhood mortality caused by rotavirus is relatively low in the U.S. Estimates of death resulting from complications of rotavirus are from 20[xxiii] to 100 deaths per year. From 1979 through 1985, an average of 500 children died annually from diarrhea disease in the United States; an estimated 20% of these deaths were caused by rotavirus infection. Death rates for diarrhea disease were highest in

the South and among black children less than 6 months of age. Many deaths and hospitalizations may be prevented by the aggressive use of oral rehydration therapy, which is underused. Children 6 months to 2 years of age, premature infants, the elderly, and the immuno-compromised are particularly prone to more severe symptoms caused by infection with Group A rotavirus. Outbreaks of Group A rotavirus diarrhea are common among hospitalized infants, young children attending day care centers, and elder persons in nursing homes.[xxiv]

B. Rotavirus Vaccine Development

Wyeth Lederle Vaccines and Pediatrics, a subsidiary of American Home Products was the first pharmaceutical company to come to market with a rotavirus vaccine. The Rotashield was approved by the Food and Drug Administration on August 31, 1998. It was a Rhesus monkey-based live oral vaccine. Merck was also developing a rotavirus vaccine that was based on bovine cells. The National Institute of Allergy and Infectious Diseases was conducting research in rotavirus vaccine development. Smith Kline Beecham was also working on a rotavirus vaccine.

Wyeth-Lederle Vaccines and Pediatrics first filed their Investigational New Drug Application in August of 1987 for the Rotashield vaccine. This vaccine had an overall relative efficacy of 49% to 83% for four strains of rotavirus.

C. Timeline for Vaccine Approval and Universal Use Recommendation

Date Individual or Organization Action August 1, 1987 Wyeth Lederle Filed Investigational New Drug (IND) Application to the FDA December 9, 1994 Fred Clark, Paul Offit, Stanley Plotkin (Inventors); Wistar Institute of Anatomy and Biology and Children's Hospital of Pennsylvania (Assignees) Filed U.S. Patent for Rotavirus reassortant vaccine. Application number 353547 June 1, 1995 Fred Clark, Paul Offit, Stanley Plotkin (Inventors); Wistar Institute of Anatomy & Biology and Children's Hospital of Philadelphia (Assignees) Filed U.S. Patent for rotavirus reassortant vaccine. Application number 456906 May 6, 1997 Fred Clark, Paul Offit, Stanley Plotkin (Inventors); Wistar Institute of Anatomy and Biology and Children's Hospital of Pennsylvania (Assignees) Awarded U.S. Patent # 5,626,851 for Rotavirus Reassortant vaccine. December 12, 1997

VRBPAC (FDA) The committee voted to recommend that the FDA license the Rotashield vaccine. February 11, 1998

ACIP (CDC) The committee voted to include the statement "Routine Vaccination" in the ACIP statement. June 25, 1998

ACIP (CDC) The committee voted to include the short version of the ACIP statement regarding post-marketing surveillance. August 31, 1998 FDA

FDA approved the Rotashield vaccine. October 1, 1998 Wyeth-Lederle

Distribution of the Rotashield began. October 21-22, 1998

ACIP (CDC) The committee voted to add the rotavirus vaccine to the Vaccines For Children Program. January 15, 1999

CDC

ACIP published its recommended immunization schedule in the Morbidity and Mortality Weekly Report (MMWR). February 17-18, 1999

ACIP (CDC) The committee voted in favor of recommending immunization of infants who have diarrhea at the time presented for immunization. February 17-18, 1999

ACIP (CDC) The committee voted to include infants born prematurely under guidelines for routine immunization with a precaution to insure the infant was at least six weeks of age, leaving a nursery or no longer hospitalized, and clinically stable. March 19, 1999

CDC

CDC officially adopted recommendation for routine use of rotavirus vaccine as published in MMWR. May 1999

FDA

Ten cases of intussusception reported through the VAERS System. June 17, 1999

ACIP (CDC) The ACIP discussed intussusception reports to the Vaccine Adverse Event Reporting System (VAERS) July 16, 1999

CDC

MMWR published request to suspend use of Rotashield until further analysis of existing reports of intussusception. October 15, 1999 Wyeth-Lederle

A subsidiary of American Home Products Manufacturer voluntarily removed Rotashield from the U.S. market. October 22, 1999 ACIP (CDC) The Committee voted to rescind the Recommendation of the Rotashield Rotavirus Vaccine.

D. Severe Bowel Obstructions Tied to Rotashield Vaccine

A little more than one year after the Rotashield rotavirus vaccine was licensed by the Food and Drug Administration as a safe and effective vaccine, it was removed from the market due to adverse events. More than 100 cases of severe bowel obstruction, or intussusception, were reported in children who had received the vaccine were reported.

Rotashield was licensed by FDA on August 31, 1998. Distribution began on October 1, 1998. On January 1, 1999 there were zero cases of intussusception on the Vaccine Adverse Events Reporting System (VAERS). In May 1999 there were ten cases of intussusception reported in the VAERS. Data was received from the Northern California Kaiser active surveillance system and from statewide data case control in Minnesota in early June that supported a relationship between the Rotashield vaccine and intussusception. Dr. Jeffery P. Koplan, Director of the CDC was briefed for the first time on June 11, 1999. A subsequent meeting was held with Dr. Koplan and the CDC at which a decision was made to postpone any further use of the vaccine until further analysis was conducted. This was published in MMWR on July 16, 1999.

As of October 15, 1999, 113 cases of intussusception had been received. Nine of these reported cases were determined not to be intussusception. Of the remaining 102 cases of intussusception, 57 had received the vaccine. Of these, 29 required surgery, seven underwent bowel resection, and one five-month-old infant died after developing intussusception five days after receipt of the vaccine.[xxv] A case study was conducted that estimated that the risk of intussusception was increased by sixty percent among children who received the Rotashield.

It is alarming that it was known during clinical trials and the licensing process that there were increased incidences of intussusception in vaccinated infants. The topic was raised at a VRBPAC meeting and a reference to intussusception is listed in the ACIP recommendation, however, the committee apparently determined that the reported rate of 1 in 2010 was not to be statistically significant. The CDC continues to provide inconsistent information on their web site. One fact sheet, the Rotavirus Q & A, has not been updated since July 16, 1999 and does not provide a link to a more recent fact sheet. The fact sheet significantly plays down the seriousness of the adverse event

and asserts that no association has been made.[xxvi] Another Rotavirus Vaccine Fact Sheet was updated on February 2, 2000 that indicates that the FDA and CDC confirmed the association between Rotashield and intussusception.

During the clinical trials, five children out of a total of 10,054 subjects suffered intussusception.[xxvii] If confirmed, the rate of intussusception would be 1 in 2010 children. According to the manufacturers package insert, the adverse event was considered statistically insignificant at 0.05%. Intussusception had not previously been associated with natural rotavirus infection.

Rotashield rotavirus vaccine was removed from the U.S. market in October 1999. Development of other rotavirus vaccines continues by Merck and others.

Section IV

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee

A. Vaccines and Related Biological Products Advisory Committee:

1. Description of the Committee:

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) advises the Commissioner of the Food and Drug Administration in discharging her responsibilities as they relate to helping ensure safe and effective biological products, including vaccines.[xxviii] It reviews and evaluates the data concerning the safety, effectiveness, and the appropriate use of vaccines and related biological products. In short, the VRBPAC advises the FDA on whether or not to license new vaccines for commercial use.

2. Membership of the Committee:

The VRBPAC has 15 voting members, including the Chair, who are selected by the Commissioner of the FDA or her designee. The FDA seeks members who are "authorities" in the fields of immunology, pediatrics, infectious diseases and related fields. The charter also suggests that there be a member who is identified with consumer interests. VRBPAC meets approximately 6 times a year.

3. Terms:

VRBPAC members serve overlapping terms of four years. A member may serve after the expiration of the members term until a successor has taken office. Under the DHHS policy, members may not serve continuously for more than four years or more than eight years within a twelve year period. Additionally, members may not serve on more than one committee within the agency at the same time. Vacancies are announced at least once a year in the Federal Register. The selections are made by Dr. Linda Suydam, Senior Associate Commissioner of the FDA, who also considers and grants all conflict of interest waivers.

4. Temporary voting members:

Members of other scientific and technical FDA advisory committees -- not to exceed 4 members (Exhibit 54) -- may vote on the VRBPAC when: a.) expertise is required that is not available among current voting members or, b.) their presence is needed to comprise a quorum.

B. Conflict of Interest Review and Waivers by the FDA

1. Scope:

As discussed in Section I of this report, conflict of interest statutes and regulations generally prohibit the participation of advisory committee members in official matters where that person has a financial interest and their participation will have a direct and predictable effect on that interest.[xxix] Many factors are considered by the Department in determining whether a conflict of interest exists and, if it

does, whether it may be waived to allow participation. A conflict may either be an actual or apparent conflict. An actual conflict is the situation where a direct, identifiable conflict exists. An apparent conflict is where there is an appearance of a lack of impartiality.[xxx]

2. Procedure:

There are many steps in the FDA's procedure to clear potential conflict of interests in VRBPAC.

They include:

a. Prior to a scheduled VRBPAC meeting, FDA officials will review the agenda and other assignments. Entities with a financial interest in the matter to be discussed are identified by the staff of the Center for Biologics Evaluation & Research, as are the products to be used in conjunction with the product being reviewed, and competing products.

b. Advisory committee members are required to fill out a Confidential Financial Disclosure Statement (FDA form 3410) prior to each meeting.

c. FDA staff compares financial disclosure information compiled for each VRBPAC member with the issues on the agenda for the upcoming meeting to determine who has conflicts. Based on the information provided, the member can be found to have: a.) no conflict of interest, b.) a conflict of interest that is minimal and thus, justifiable, or c.) a conflict of interest so substantial that a waiver is the only course of action. If there is a substantial conflict of interest, it must be detailed. Some of the factors and criteria used in determining whether a waiver is appropriate include:

(i.) Agenda topic: Where the subject of the meeting is of a general scientific presentations and not of particular products or to review research with no direct or predictable effect on outside interests, waivers are not needed.[xxxii]

(ii.) Net worth of member: The amount of the financial interest will be considered in relation to the net worth of the SGE.[xxxiii]

(iii.) Employment: Situations where the SGE's university employer has a grant or a contract with either the sponsoring company or any other affected companies will be taken into consideration during the waiver process.[xxxiiii]

(iv.) Amount of grant or contract: The amount of the grant or contract given to the university employer of a member, as well as the member's involvement (i.e. principal investigator, department chair) will be considered in whether the financial interest arises to the point of conflict. (Exhibit 53).

(v.) Competing products: The member's financial interest in competing products or otherwise affected companies will be taken into consideration by the agency in determining whether a waiver may be granted.[xxxv]

(vi.) Potential effect of committee recommendation: Members may not vote on any matter where a committee recommendation could benefit financially either the member or his/her immediate family. A waiver may not be granted where the member's own research is involved.

(vii.) Industry consultant or advisor: The level of involvement of the member with either a sponsoring or an affected company, as measured by the amount of compensation received, will also be considered. (Exhibit 53).

(viii.) Patents, royalties and trademarks: As in the previous categories, the level of involvement of the particular member will be measured by the amount of compensation received from the sponsoring or affected companies. (Exhibit 53).

b. If the Director of the division determines that the member's services are too important, despite a substantial conflict of interest, he must provide the necessary justification for a waiver. Where the financial interest is relatively large it is essential that the justification be particularly strong.[xxxvi]

c. If a waiver is contemplated, it must be reviewed by FDA's ethics staff who will make a recommendation to the approving official regarding the waiver. They may also consult with the Office of General Counsel in the Department or the Office of Government Ethics.

d. Final approval of waivers is given by Dr. Linda Suydam, Senior Associate Commissioner of the FDA. In addition to a full participation waiver, the Department may also grant:

i.) Limited Waivers: This waiver places restrictions on the member's participation, such as no right

to vote.[xxxvi] Potentially, a limited waiver could also restrict a member's participation to answering factual questions about the matter being discussed by the committee.

ii.) Disclosure: In cases where the financial interest is not deemed to be substantial, it will be disclosed in the public record with the expectation that other participants will take them into consideration as they evaluate the opinions expressed by the member. The Agency in some cases deems that such disclosure is sufficient in addressing the potential for an actual or apparent conflict of interest.[xxxvii]

iii.) Recusal: Finally, members are expected to recuse themselves from the committee proceedings in cases where they deem that the financial interest may interfere with their ability to be impartial.

C. Problems identified with VRBPAC:

The Committee conducted an in-depth investigation of the VRBPAC from 1995 to present. As noted above, the approval and recommendation of the Rotashield vaccine for the treatment of rotavirus was chosen as a good example of the concerns that arise from the use of waivers by advisory committees. For the purposes of this report, we chose the VRBPAC's December 12, 1997, meeting, at which the Rotashield vaccine received its initial approval.

This meeting was attended by 5 VRBPAC committee members, 5 temporary voting members and at least 3 consultants, in addition to both the FDA and the sponsor company's representatives. Although Wyeth-Ayerst Laboratories (Wyeth Lederle Vaccines and Pediatrics) was the sponsoring company for the Rotashield vaccine, several other companies were deemed to be Affected Companies by the FDA. These include: Merck, Virus Research Institute, and National Institute on Allergy and Infectious Diseases (NIAID). Advisory committee members, temporary voting members and consultants were screened for potential financial conflicts of interest with either the sponsoring or the affected companies. The decision to recommend approval of the license for the Rotashield was unanimous. The Government Reform Committee's investigation of the VRBPAC's Rotashield vaccine approval meeting raised several concerns:

1. Unanimous vote despite concerns raised: At the VRBPAC meeting, several members raised concerns about adverse effects that occurred at the rotavirus clinical trials. These included: intussusception, infant's failure to thrive, and febrile reactions among others.

A statement by Dr. Fleming, a temporary voting member, summarizes the statements of many of the other voting members. He stated: "And as a result, I would ask the FDA to work with the sponsor to further quantitate what these serious side effects are -- specifically the adverse effects, driven in particular by febrile illness -- is inducing hospitalizations and what is that level of access. I still don't feel like I have a good grasp of that at this point." He proceeded to vote for the approval recommendation.[xxxviii]

2. Potential conflicts of interest of VRBPAC members: Four out of five members had conflicts of interest that necessitated waivers. Perhaps one of the major problems contributing to the overall influence of the pharmaceutical industry over the vaccine approval and recommendation process may be the loose standards that are used by the agency in determining whether a conflict actually exists. (Exhibit 53). In many cases, significant conflicts of interest are not deemed to be conflicts at all.

For this particular meeting, two members of the VRBPAC were excluded from the committee deliberations:

a.) Dr. Harry Greenberg: Dr. Greenberg was excluded from the deliberations as he is a patent holder of the Rotashield, the actual vaccine discussed at the meeting. He may have been present at the VRBPAC meeting, but it is not apparent that he participated in any way, including the open public session.

b.) Dr. Clements-Mann: It is not clear from the waiver process why she was excluded from participating in the proceedings.[xxxix] However, while Dr. Clements-Mann did not vote, she was present and did participate in the public session of the committee deliberations. Dr. Clements-Mann works for the Johns Hopkins University.

Five members out of fifteen members of the advisory committee were present in the deliberations:

c.) Dr. Patricia Ferrieri, Chair: She directed the discussion on the Rotashield vaccine. At the time of the proceedings, Dr. Ferrieri owned at about \$20,000 of stock in Merck, an affected company and manufacturer of an upcoming rotavirus vaccine. This conflict was waived by the FDA as it was deemed to be of low involvement (Exhibit 56). Also, Dr. Ferrieri received a \$135,000 NIAID grant for unspecified research on rotavirus[xl] for 1998-1999, after the committee voted to approve the Rotashield vaccine. It is not certain whether this grant was in negotiations at the time of the VRBPAC vote on Rotashield. Dr. Ferrieri received a full participation waiver.

d.) Dr. Caroline Hall: At the time of the VRBPAC meeting for approval of Rotashield, Dr. Hall's employer, the University of Rochester, had a \$9,586,000 contract with the NIAID for a rotavirus vaccine. As the original developer of the rotavirus vaccine, the NIAID subsequently licensed to Wyeth the rights to further develop the Rotashield vaccine. According to the conflict of interest waiver forms, neither Dr. Hall nor the principal investigator of the NIAID contract have evaluated the specific Rotashield vaccine. However, the same form states that it is unknown which rotavirus vaccine was licensed to Wyeth from NIAID. Dr. Hall was allowed to fully participate in the meeting.

e.) Ms. Rebecca Cole: The consumer representative on the VRBPAC committee at the time, Ms. Cole has been an ardent advocate for increased vaccinations after her son died of complications from his asthmatic condition and the chicken pox. As an advocate for vaccines, she has received both travel expenses and honoraria from Merck, the developer of the chicken pox vaccine, to appear in discussions advocating its use. Under the FDA standard, Ms. Cole did not need a waiver for participation.

f.) Dr. Kathryn Edwards: Dr. Edwards received a contract from Wyeth Lederle for \$255,023 per year from 1996 to 1998 for the study of pneumococcal vaccines. She also had numerous grants and contracts with the NIAID, an affected company, for the following amounts: \$206,750 per year from 4/1/95 to 3/1/98 to study TB vaccines; \$673, 373 a year from 1996-2003 to study mucosal vaccines; and \$86,279 from 1997-1998 to study acellular pertussis/cell mediate immunity. These contracts and grants were deemed to potentially appear to be a conflict, but were subsequently waived. Dr. Edwards was allowed full participation in the meeting.

g.) Dr. Mary Estes: At the time of the Rotashield approval meeting, Dr. Estes' employer, Baylor College of Medicine, was receiving a large amount of funds for the development of rotavirus vaccines, including a \$75,000 grant from American Home Products, the parent company of Wyeth-Lederle Vaccines and Pediatrics, and from the NIAID for \$404,000 from 8/93 to 7/98. The FDA determined that the amount of funding is not large and represent[ed] a small portion of the University's research budget. (Exhibit 61) Accordingly, this conflict was waived. Dr. Estes was also listed as the principal investigator for a grant from Merck for the development of a rotavirus vaccine. This conflict was also waived and Dr. Estes was given a full participation waiver for the meeting.

3. Use of temporary voting members:

An additional concern was raised by the liberal use of temporary voting members, particularly in the Rotashield approval meeting of VRBPAC. Of the ten (10) members allowed to vote in this meeting, only half (5) were standing members. The other half were temporary voting members. The VRBPAC charter states that the number of temporary members is normally not to exceed four members.[xli]

This is bothersome as a meeting where a quorum cannot be constituted from the duly appointed members should be canceled until the quorum can be achieved. The temporary voting members appointed for this meeting were:

- a.) **Dr. Claire Broome:** Senior Advisor to the Director for Integrated Health Information Systems at the Centers for Disease Control.
- b.) **Dr. Dixie Snider:** Associate Director for Science at the Centers for Disease Control. Dr. Snider was, at the time, the Executive Secretary of the CDC's Advisory Committee on Immunization Practices (ACIP).
- c.) **Dr. David Karzon:** Professor at Vanderbilt University. Dr. Karzon is a frequent consultant and/or temporary voting member to the VRBPAC, voting on a variety of issues. While no apparent conflicts of interest were reported by Dr. Karzon, his employer, Vanderbilt University, receives extensive grants and contracts from pharmaceutical companies.
- d.) **Herbert DuPont:** Professor at the University of Texas in Houston. No apparent conflicts of interest were reported.
- e.) **Thomas Fleming:** Chair of Biostatistics at the University of Washington, Dr. Fleming has also been a frequent temporary voting member or consultant to the VRBPAC.

4. Conflicts of interest of consultants:

At least three consultants participated in the discussion of the Rotashield vaccine on December 12, 1997. They were:

a.) **Dr. Neal Halsey:** Dr. Halsey has been one of the leading investigators and advocates in the area of vaccines. In addition to numerous grants and contracts from different vaccine manufacturers, Dr. Halsey has received frequent reimbursements for travel expenses and honoraria from companies such as Merck. Importantly, at the time of the Rotashield approval meeting, Dr. Halsey was seeking start-up funds from most of the vaccine manufacturers for the establishment of an institute for vaccine safety at Johns Hopkins University, where he works. He has already received \$50,000 from Merck and was awaiting funds from Wyeth Lederle (Exhibit 56). Dr. Halsey also participated in the rotavirus working group of the ACIP.[xlii] Also, Dr. Halsey was the Chair of the Committee on Infectious Diseases and representative of the American Academy of Pediatrics which, in conjunction with the CDC, sets and advertises the recommendations for schedules and dosages of immunizations. He was granted a waiver for participation,[xliii] participated during the morning session and then recused himself at the beginning of the afternoon session due to conflicts that were not disclosed in the minutes for the meeting. Finally, Dr. Halsey's employer, Johns Hopkins University, is also the employer of Dr. Clements-Mann, who was excluded from the discussions.

b.) **Dr. Yvonne Maldonado:** No apparent conflicts were listed for Dr. Maldonado.

c.) **Dr. John Modlin:** At the time of the Rotashield approval meeting, Dr. Modlin owned approximately \$26,000 in Merck stock, an affected company. He has also served on Merck's Immunization Advisory Board from 1996 to the present. These financial interests were waived and he was allowed to extensively participate in the meeting although, as a consultant, he was not allowed to vote. Also, Dr. Modlin was at the time the Chairman of the ACIP and its rotavirus working group.

5. Balanced representation:

As previously discussed, the statutory requirement of balanced representation is one of the most controversial provisions of the FACA. The FDA has interpreted "balance" as diversity of geography, ethnicity, disciplines and gender. While it is questionable whether this standard guarantees the balance of points of view represented expressly required by the statute, it was interesting to see the high concentration of professors in pediatrics represented on the VRBPAC committee, particularly during the Rotashield discussion (Dr. Ferrieri, Dr. Karzon, Dr. Edwards, Dr. Modlin, and Dr. Halsey).

Also, two of the voting members work for Vanderbilt University (Dr. Edwards & Dr. Karzon), while one member Dr. Clements-Mann (who, although excluded from voting, was able to participate in the open public hearing part of the meeting) and Dr. Halsey, both come from Johns Hopkins University. Two of the voting members (Dr. Broome and Dr. Snider) are CDC Federal employees. The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry.

6. Recurrent membership:

A troubling pattern is the recurrence of members, temporary voting members and consultants, year after year, despite term limits, which greatly limits the diversity of opinion that is sought in this type of committee.[xliv] After reviewing the VRBPAC rosters of members and consultants for the past few years, it becomes apparent that many of the members have frequently participated in committee proceedings for many years. Also, it is evident that there is a significant number of people who frequently participate in proceedings at both the FDA and the CDC, despite a policy that prohibits the simultaneous participation of members in more than one advisory committee within the agency.[xlv] In this particular meeting, at least four of the members (Dr. Broome, Dr. Snider, Dr. Modlin and Dr. Halsey) were intrinsically involved in the development of recommendations for the CDC. In other words, these persons influence the process of vaccine approval and recommendation. Dr. Halsey also chaired the American Academy of Pediatrics committee which helps set and advertise the schedule and dosage of recommended vaccines. Also, several of the temporary voting members frequently participate in VRBPAC's meeting, without actually becoming members, thus severely limiting the diversity of participation and opinion.[xlvi] Other members are retained as temporary voting members and/or consultants once their four year term on the advisory committee has expired.[xlvii]

7. Timing of the proceedings:

A particularly troubling aspect of the deliberations on the Rotashield vaccine is the sequence of events. The ACIP Committee voted to recommend universal vaccinations of infants before the FDA licensure of the vaccine. Officials of the CDC acknowledge that they knew of no other instance where this has happened. As discussed before, during the December 12, 1997, VRBPAC vote to recommend the licensure of the Rotashield vaccine, a number of concerns were raised by some of the members with regard to the vaccine and its possible adverse effects. Although the VRBPAC unanimously approved the vaccine recommendation, some of the committee members votes were conditioned on the FDA's ability to successfully resolve the areas of concern. However, before the FDA final licensure of the Rotashield vaccine in August 1998, the ACIP committee - as will be discussed in the ACIP section of this report- had already voted to recommend the mandatory universal use of the vaccine. This is troubling, not only because the vaccine had not yet been approved by the FDA, but because there were several areas of concerns that may not have been successfully addressed by the FDA, at the time of the ACIP vote.

Section V

Centers for Disease Control and Prevention

The Advisory Committee on Immunizations Practices

A. Practices and Procedures of the Advisory Committee on Immunization Practices (ACIP)

1. Purpose of the ACIP

ACIP provides advice and guidance on vaccine policy to the Secretary of DHHS, the Assistant Secretary for Health, and the Director of CDC. The ACIP develops written recommendations, subject to the approval of the Director of the CDC, for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

The recommendation for routine use of a vaccine is tantamount to a Federal mandate for vaccine use. HHS regulations require that all grants for childhood immunizations are subject to the States' implementation of procedures to ensure routine vaccination. To receive federal funding the States must, among other things, require a plan to systematically immunize susceptible children at school entry through vigorous enforcement of school immunization laws.[xlvi]

Additionally, the ACIP has been given a mandate from Congress by the Omnibus Budget Reconciliation Act of 1993, to establish and periodically review and, as appropriate, revise a list of vaccines for administration to children in the Vaccine For Children Program (VFC), along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the pediatric vaccines.[xlvii] The VFC program provides for public purchase of vaccines for children without health insurance coverage. Under the VFC program, \$474 million has been obligated to pay for the purchase of vaccines in fiscal year 2000.

2. Membership of the ACIP

The ACIP has three different categories of membership consisting of voting members, ex-officio members and liaison representatives.

a. Voting Members of the ACIP

The ACIP has twelve voting members, including the Chair, all approved by the Secretary of DHHS or his designee.[i] The ACIP members are selected based upon their expertise in the field of immunization practices.[ii] The membership consists of U.S. citizens that have multi-disciplinary expertise in public health, and expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine. The ACIP membership is required by FACA and agency guidelines to be fairly balanced in terms of point of view represented and the committee's function. Specifically, the CDC attempts to select members from diverse backgrounds including geographic areas, gender, ethnic and minority groups, and the disabled.

(i.) Procedure for nomination to the ACIP

New members are nominated to the ACIP on an annual basis. Suggestions for membership to the committee are sought from a variety of sources including current and former ACIP members, professional societies, vaccine manufacturers and the general public. A panel of government officials screens the candidates for nomination to the committee and submits a slate of possible nominees to the director of the CDC. With approval of the CDC director, a nomination package is prepared for the Secretary of DHHS who makes the official appointments to the committee.

Committee members are nominated to serve for overlapping four-year terms. Members may serve after the expiration of their terms until their successors have taken office.[iii]

b. Ex Officio Members of the ACIP

The ACIP charter designates seven non-voting ex officio members to the committee from the following federal agencies:

1. Deputy Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration
2. Deputy Director for Scientific Activities, Office for the Assistant Secretary of Defense
3. Under Secretary for Health, Department of Veterans Affairs
4. Director, National Center for Drugs and Biologics, Food and Drug Administration (FDA)
5. Medical Advisor, Medicaid Bureau, Health Care Financing Administration (HVFA)
6. Director, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, HHS
7. Director, National Vaccine Program Office, CDC[liii]

Generally, designees of the officials listed above hold the ex officio positions. In contrast to regular voting members, who are expected to voice their personal opinions, ex-officio members are expected, to the extent possible, to represent the position and views of their sponsoring organizations.[liv]

c. Liaison Members:

In addition to the voting members and ex-officio members, the ACIP charter specifies 16 additional non-voting liaison representatives from professional societies and organizations responsible for the development and execution of immunization programs for children and adults. Like ex officio members, liaison members are expected, to the extent possible, to represent the positions and views of their sponsoring organizations. Liaison members are expected to contribute to committee discussions when issues of importance to their organizations are being discussed. These members can serve as appointed consultants to working groups and subcommittees to provide expert advise and apprise the working group of the position their organization endorses.[lv]

The liaison representatives to the ACIP consist of representatives from the following organizations:

1. American Academy of Family Physicians
2. American Academy of Pediatrics
3. American Association of Health Plans
4. American College of Obstetricians and Gynecologists
5. American College of Physicians
6. American Hospital Association
7. American Medical Association
8. Association of Teachers of Preventative Medicine
9. Canadian National Advisory Committee on Immunization
10. Hospital Infection Control Practices Advisory Committee, CDC
11. Infectious Diseases Society of America
12. National Medical Association
13. Pharmaceutical Research and Manufacturers of America
14. National Vaccine Advisory Committee
15. Biotechnology Industry Organization
16. Secretario de Prevencion y control de Enfermedades, Mexico

3. Decision-Making Process of the ACIP

a. Working Groups of the ACIP

When deemed appropriate by the Executive Secretary and the Chair of the ACIP, working groups may be formed to prepare draft policy recommendations to be submitted to the full ACIP for its consideration. The working groups must: 1) include one or more regular voting members, 2) include CDC staff members, 3) may include ex officio members and liaison representatives and other consultants. Vaccine manufacturer's official representatives may not serve on working groups but, at the discretion of the chair, may be consultants to a working group.[lvi]

Generally, working groups range from six to fifteen members.[lvii] The working group is charged with reviewing all pertinent information relative to the recommendation for use of a vaccine. No notice is given to the public of working group meetings and discussions of the group are held in private. No minutes are taken at the meetings.

Upon drafting a proposed recommendation, the chair will submit the draft proposal to the ACIP for consideration. The ACIP members review the proposal and suggest revisions to the working group. This process is generally repeated numerous times. The process for making a final recommendation to the full ACIP generally takes eighteen to twenty-four months. The work that the working group does contributes in large part to the recommendations for use of a vaccine submitted to the Director for approval.

b. Full Meetings of the ACIP

Regularly scheduled meetings are usually held three times a year, at the discretion of the CDC, with meeting dates announced six to twelve months in advance. Notices of each meeting, along with agenda items that may be discussed, are published in the Federal Register in accordance with the requirements of FACA. Potential topics for ACIP consideration can be suggested by anyone, but are most often proposed by CDC program staff, ACIP members, and vaccine manufacturers.[lviii]

The meetings of the ACIP are held in public and are widely attended by representatives from government, industry, and other interested parties. Frequent votes are taken to decide on a given policy matter at hand. Whenever six or more members are not eligible to vote by reason of financial conflict or interest, the Executive Secretary has the authority to temporarily designate the ex-officio members as voting members.

c. Final Recommendations for Vaccine Use

ACIP recommendations are submitted to the agency for approval. Upon acceptance by the agency, ACIP recommendations are published in the *Morbidity and Mortality Weekly Report* Recommendations and Report published by the CDC. While the recommendations by the ACIP to the CDC are subject to agency approval, longtime CDC officials do not remember an ACIP recommendation that was not approved by the agency.[lix]

B. The ACIP Conflicts of Interest Resolution Process

1. Disclosure Requirements for ACIP Members As an SGE, every member of the ACIP is required to file the standard OGE form 450 confidential financial disclosure report once a year.[lx] New members of the ACIP must file a new entrant report no later than 30 days after assuming their position. All reports must cover the 12 months preceding the date of filing. Members must report specific sources of earned income over \$200 for the filer and \$1,000 for the filer's spouse. ACIP members must report all honoraria received in excess of \$200, along with the date services were provided. The \$1,000 threshold for spousal earned income does not apply to honoraria, because of special concerns about that form of income.[lxi] They must also report all assets held for investment or the production of income with a fair market value greater than \$1,000 at the end of the reporting period. The filer does not have to report the dollar amount or values for any asset or income.[lxii]

2. Reviewer's Responsibilities

The ACIP Deputy Ethics Officer, Mr. Joseph Carter, is responsible for ensuring that the OGE 450 is completely and properly filled out. Specifically, the reviewer is required by the OGE to check for the completeness of the financial disclosure form and that each asset and source of income are listed separately.

3. ACIP Waiver Process

Waivers are granted to each and every member of the ACIP whether or not they have conflicts of interests listed on their OGE 450. The ACIP issues "limited" 208 (B)(3) waivers on an annual basis to members who have potential conflicts of interest. The waivers allow members to participate in all matters that come before the ACIP, with the provisos that: (1) members recuse themselves from voting on matters involving vaccine-related entities where they have a current direct financial interest and (2) that they publicly disclose all relevant financial interests at the beginning of each ACIP meeting.

The waiver states that under Section 208(a) the members are under statutory obligation to refrain from participating in any deliberation that involves a particular matter having a direct and predictable effect on a financial interest attributed to them. They provide that the deputy ethics counselor has the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting the ACIP member to participate in

such matters as deemed appropriate.[ixiii]

Waivers are requested by the Executive Secretary of the ACIP, Dr. Dixie Snyder, Jr. CDC Legal Counsel Kevin Malone concurs that the waiver is appropriate and the Deputy Ethics Counselor, Mr. Joseph R. Carter, is responsible for approving the waiver. In interviewing these individuals, the Committee staff was told, "we generally give them to everyone...we give them out freely." The CDC representatives explained, it is "the nature of the industry that they will have conflicts...we will allow you to participate if you disclose your conflicts...we will let you discuss but not vote." [ixiv]

4. Work Sheets

The Executive Secretary prepares a work sheet prior to every ACIP meeting detailing the conflicts of interest that members may have pertaining to the topics on the agenda. The work sheet is only for his use and is not disclosed to the public. The documents are considered informal and are not saved by the CDC.

C. Problems Identified During the Committee's Investigation

The Committee staff's review of the ACIP's consideration of the rotavirus vaccine identified serious weaknesses in the CDC's policing of conflicts of interest on this advisory committee. On June 25, 1998, the ACIP voted to recommend the rotavirus vaccine for routine use in infants. In reviewing the minutes of ACIP meetings and the financial disclosure forms of the ACIP members, the Committee staff identified a number of troubling issues:

1. ACIP Members Do Not Fully Disclose Conflicts of Interest

Examination of ACIP members' financial disclosure forms reveals that many members do not fill them out completely. CDC ethics officials conceded to Committee staff that they have been lax in compelling the ACIP members to provide complete and thorough information.[ixv]

a. Dr. Mary (Mimi) Glodé (Exhibits 3-15)

Dr. Glodé lists reviews of medical legal cases on her OGE 450 for 1996, 1997, 1998, 1099 at 5 per year for her and her spouse, but does not detail the law firms or clients for whom they do the legal work. She only discloses that the maximum income allowed by University of Colorado is \$10,000 per year.

Dr. Glodé and her spouse have attended numerous conferences and received honoraria for their attendance. However, she does not list who the sponsors were in 1995, 1996, 1997, 1998, 1999. She states only that the honoraria given was from \$500-\$750 Per occurrence and were limited to five per year; her spouse does 5-10 per year as well.

On her 1996 FDA financial disclosure form she lists that she was a co-principal investigator on an \$84,500 grant from Chiron to study the MGNIN C Vaccine, \$10,000 of which was a part of her salary. The study lasted for fifteen months from 10/96-3/98. But on her CDC financial disclosure forms for 1997, 1998, and 1999, this funding was not mentioned as required. Furthermore, the conflict was not mentioned on the waivers granted to her by the CDC for the same years. According to the Federal conflict of interest statutes she would not be able to participate in any deliberations regarding Chiron before the ACIP.

b. Dr. Marie Griffin

Dr. Griffin doesn't fill out a new form each year. She references previous year's forms instead and adds any new items to the current year's form. (Exhibit 18)

She lists "publicly traded stock," but not the specific companies on her 10/6/94, 2/95, 6/9/96, and 10/20/97 OGE 450. This is not sufficient under the law. (Exhibit 16)

c. Dr. Paul Offit

Dr. Offit lists that he is a consultant to Merck on an attachment to his OGE 450, but does not

disclose whether or not he received any remuneration for his services. (Exhibit 39)

d. Dr. Richard Clover

Dr. Clover lists legal fees paid by the law firm of O'Bryan, Brown, and Toner, but not their client. (Exhibit 1)

The CDC informed the Committee staff that they have been unhappy with the OGE 450 and are working on a supplemental form. They stated that they wanted a form that was more specific and easier to fill out. Two years ago at the June 24-25, 1998, ACIP meeting, CDC Legal Counsel Kevin Malone stated his concerns to the ACIP:

"The 450 is a very frustrating form. All of us use the same form too and it is very difficult to even figure out what it is you should be disclosing. One of the things we've talked about is producing a supplementary form that would more explicitly lay out types of issues because certainly if we're going to be in a position that we have to be announcing these interests, we would also need to feel a little bit more confident, I think that everything is being reported." [ixvi]

However, two years later, the supplemental form has yet to be put into use.

2. Every Member of the ACIP is Granted a 208 (B) Waiver for the Entire Year

The CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year. In contrast, the FDA grants waivers on a meeting by meeting basis, taking into consideration the issues on the agenda and the affected companies discussed. Moreover, the FDA provides a list of parties that will be affected by their vote so their members clearly understand when they can not participate.

The CDC's policy of issuing annual waivers creates an environment where people do not take the conflict of interest issue as seriously as they should. This policy, in concert with sloppy monitoring of the completeness of members' financial disclosure statements, allows for a clubby environment where ethical concerns are downplayed.

3. ACIP Members are Allowed to Vote on Vaccine Recommendations, Even When They Have Financial Ties to Drug Companies Developing Related or Similar Vaccines

Members of the ACIP are allowed to vote on a recommendation for one company's vaccine even if they have financial ties to a competing firm developing a similar vaccine. For example, in the case of rotavirus vaccine, the vaccine before the advisory committee was developed by Wyeth-Lederle. However, Merck and Smithkline-Beecham had rotavirus vaccines under development. A recommendation for Wyeth-Lederle's vaccine would help pave the way for future recommendations for the products of Merck and Smithkline-Beecham.

While ACIP members with ties to Wyeth-Lederle were not allowed to vote on recommendations for the rotavirus vaccine, those with ties to Merck and Smithkline-Beecham were allowed to vote. This stands in stark contrast to the policies of the FDA. In discussions with FDA staff on this specific issue they informed the Committee staff that when the VRBPAC is deliberating the licensure of a vaccine, a company is considered affected [an affected company is one with a direct interest] if they are direct competitors of the manufacturer of the vaccine being considered. They further clarified that that this policy was in place because of the competing interest of the affected company and not because of concerns about the release of proprietary information. Moreover, if a VRBPAC member has a direct interest with a competing firm they are automatically disqualified from participation.

At ACIP meetings from February 11, 1998, through June 17, 1999, there were eight votes related to the their approval of the rotavirus vaccine for routine use. Three of these votes were particularly notable. They include: (1) June 25, 1998 - The ACIP approved the statement recommending the rotavirus vaccine for routine use, (2) October 22, 1998 - The ACIP recommended the rotavirus

vaccine be added to the Vaccines for Children Program, and (3) October 22, 1999-the ACIP rescinded its earlier decision to recommend the rotavirus vaccine.

a. Dr. John Modlin-Chair beginning 2/11/98 (Exhibits 35-37)

Dr. Modlin owned 600 shares of stock in Merck as listed on his OGE 450. He serves on Merck's Immunization Advisory Board but receives no remuneration. Dr. Modlin informed committee staff that he divested his shares in Merck some time in 1999.

Dr. Modlin was the Chairman of the Rotavirus working group. He voted yes on eight different matters pertaining to the ACIP's rotavirus statement, including recommending for routine use and for inclusion in the VFC program.

b. Dr. Paul Offit (Exhibits 38-41)

Dr. Offit shares the patent on the Rotavirus vaccine in development by Merck and lists a \$350,000 grant from Merck for Rotavirus vaccine development. Also, he lists that he is a consultant to Merck.

Dr. Offit began his tenure on ACIP in October of 1998. Out of four votes pertaining to the ACIP's rotavirus statement he voted "yes" three times, including, voting for the inclusion of the rotavirus vaccine in the VFC program.

Dr. Offit abstained from voting on the ACIP's rescission of the recommendation of the rotavirus vaccine for routine use. He stated at the meeting, "I'm not conflicted with Wyeth, but because I consult with Merck on the development of rotavirus vaccine, I would still prefer to abstain because it creates a perception of conflict." [lxvii]

c. Dr. Fernando Guerra (Exhibits 30-31)

Dr. Guerra lists a Contract with Merck Vaccine Division from 2/99-8/99 on his OGE 450, and a donation of \$25,000 by Merck, Pasteur Merieux Connaught, and Medimmune (5/11/99 supplement to OGE 450). Also, he has a Contract with Smithkline-Beecham as a Principal Investigator (pending 7/99).

Dr. Guerra voted yes on eight different matters pertaining to the ACIP's rotavirus statement, including recommending for routine use and for inclusion in the VFC program.

d. Dr. Marie Griffin (Exhibits 16-29)

Dr. Griffin lists consultant fees (3/21/97) and a salary from Merck relating to her position as Chair of Merck's Endpoint Monitoring Committee on her OGE 450 (5/12/98 & 1/22/98).

She also lists consulting fees and travel expenses paid by Merck. (Exhibit 22)
Her spouse is a consultant for American Cyanamid (5/12/98 disclosure). American Cyanamid and Wyeth-Lederle are Subsidiaries/divisions of American Home Products Corporation.

Dr. Griffin voted on seven different matters (yes six times and no once) pertaining to the ACIP's rotavirus statement, including recommending yes for routine use and for inclusion in the VFC program.

d. Dr. T. Chinh Le (Exhibits 32-34)

Dr. Le's employer, Kaiser Permanente, is participating in vaccine studies with Merck, Wyeth-Lederle, and Smithkline-Beecham. Additionally, Dr. Le owns stock in Merck as reported on his OGE 450. Dr. Le abstained from voting on all but one issue related to the Rotavirus.

e. Dr. Richard Clover (Exhibits 1-2)

Dr. Clover lists educational Grants from Merck and Smithkline-Beecham on his OGE 450. He voted on seven different matters (six times and no once) pertaining to the ACIPs rotavirus statement, including recommending voting yes for routine use and for inclusion in the VFC program.

4. Members Who are Not Allowed to Vote on a Recommendation Due to Financial Conflicts are Allowed to Fully Participate in the Discussion Leading up to a Vote

The "limited" 208(B)(3) waiver process enacted by the CDC allowing for discussion in all matters before the ACIP by conflicted members appears to be in direct contradiction to common practice at other DHHS agencies.

As stated succinctly by the Congressional Research Service, "Clearly, the influence on Government policy from advice and persuasion during a "discussion" of a particular recommendation, immediately preceding a vote on that recommendation, is significant and is equal under the law, to participating in a particular recommendation by way of voting for or against that recommendation." [lxviii]

a. Inappropriate Statements by ACIP Members Undoubtedly Influence the Process

This is evidenced by several exchanges between Dr. T. Chinh Le and members of the ACIP. At one point during deliberations on the rotavirus vaccine, he said, "if I were to vote for this, I would vote for this routine immunization" and went on to encourage a two-dose regimen for the vaccine. [lix] Moreover, at the June 1998 ACIP, meeting during which they approved the statement for routine use of the rotavirus vaccine, he said he "feels very privileged to be able to participate in a discussion that he cannot vote on . . . Hopefully, that perhaps what I will say will influence the people who can vote [referring to ex officio members] for me if I cannot vote." When Committee staff queried CDC ethics officials regarding these statements, they acknowledged that they were inappropriate, and that they had discussed the issue with Dr. Le.

Dr. Le abstained from all but one vote related to the rotavirus vaccine because of significant conflicts of interest as stated earlier in this report. He did, however participate extensively in deliberations on the rotavirus vaccine and was a member of the rotavirus working group.

CDC conflict of interest policies are contrary to those of both the FDA, as cited earlier in this report, and that of the National Institutes of Health (NIH). The Office of Federal Advisory Committee Policy (OFACP) at NIH clearly states that a 208 (B)(3) waiver "is considered a 'general' waiver, in that it allows participation in matters that affect all institutions, or types of institutions, similarly. Even with a general waiver, however SGEs must disqualify themselves from participation in all matters that specifically and uniquely affect their [particular] financial interest." [lxx]

5. Liaison Representatives Don't have to Disclose Financial Conflicts of Their Organizations

Liaison representatives to the ACIP are not considered SGEs by the CDC. [lxxi] As such, they are exempted from the Federal conflict of interest statutes the financial disclosure process. In the process of investigating events leading up to the approval of the rotavirus vaccine, the Committee staff has learned that the relationship between liaison members and the ACIP is substantially more formal than described by the CDC.

ACIP liaison members provide more than the just the opinions of their organization to the advisory committee's process. Their role of the liaison representatives is more like that of a de facto SGE than an advisory representative. They are central to the process of creating recommendations for vaccine use by the ACIP. As official voting members of working groups that write draft recommendations for the committee's consideration, they are under routine supervision by CDC staff and have meetings in government offices. Moreover, their advice is solicited frequently by CDC personnel on issues where their organization has a financial interest.

In a cursory review of publicly available references and an internet search, the Committee staff was

able to find that the following organizations that the ACIP liaison representatives represent have ties to numerous vaccine manufacturers.

a. American Academy of Family Pediatrics

Abbott Laboratories, American Home Products Corporation, Aventis, Bayer Corporation, bioMerieux, Boehringer Ingelheim Chemicals Co., Bristol-Myers Squibb Company, Eli Lilly and Company, Forest Laboratories, G.D. Searle & Co., Glaxo Wellcome plc, Janssen Pharmaceutica, Lederle Laboratories, Merck & Co., Muro Pharmaceuticals, Novartis, Novo Nordisk A/S, Ortho-McNeil Pharmaceuticals, Otsuka America Pharmaceutical, Inc., Pasteur Merieux Connaught, Pfizer, Inc., Pharmacia, Schering AG, Schwarz Pharma, Inc., SmithKline Beecham, Solvay S.A., Warner-Lambert Company, and Wyeth-Ayerst Laboratories .[lxxii]

b. American Academy of Pediatrics

Abbott Laboratories, Astra, Merck & Co., Pasteur Merieux Connaught, Pfizer, Inc., and SmithKline Beecham.[lxxiii]

c. American College of Obstetricians and Gynecologists

Berlex Laboratories, Eli Lilly and Company, Novartis, Ortho McNeil Pharmaceutical, Pharmacia, Schering AG, and Wyeth-Ayerst.[lxxiv]

d. American Medical Association

Aventis, Glaxo Wellcome plc, Merck & Co., Pfizer, and Shering AG.[lxxv]

e. Infectious Disease Society of America

Aventis and Bristol-Myers Squibb Company.[lxxvi]

f. Biotechnology Industry Organization

Merck & Co., Wyeth-Ayerst and many other pharmaceutical companies.[lxxvii]

g. Pharmaceutical Research and Manufacturers of America

6. The Use of Working Groups is Contrary to the FACA (Exhibit 71)

a. Members of the Rotavirus Working Group of the ACIP

The ACIP rotavirus work group was responsible for creating the statement recommending universal use of the rotavirus vaccine. The working group has ten members, seven of whom have identifiable conflicts of interest with vaccine manufacturers or vaccine interest groups. The group's meetings were held in private with no minutes or records of the proceedings taken. It appears that members who were not allowed to vote because of conflicts of interest with Wyeth-Lederle, such as Dr. Le, were allowed to work extensively on the recommendation for a long period of time in the working group.

The broad ability to grant waivers from the federal conflict of interest statutes was specifically enacted because of the statutory requirements and safeguards of the FACA. FACA requires that advisory committees hold public meetings, except in unusual circumstances. As such, deliberations of advisory committees are open to the most exacting public scrutiny. These requirements are to ensure public scrutiny of advisory committees operations and ensure that it is not a secretive or hidden vehicle for special interest influence.[lxxviii] The ACIPs prolific use of working groups to draft vaccine policy recommendations outside the specter of public scrutiny opens the door to undo special interest access.

i. John Modlin, M.D., Chairman

Chinh T. Le, M.D.

David W. Fleming, M.D

ACIP Voting Members

Dr. Le has conflicts with Wyeth Lederle and Smithkline-Beecham and Dr. Modlin has a conflict with

Merck as described in this report.

ii. Roger I. Glass, M.D., Ph.D.

Joseph S. Bresee, M.D.

Centers for Disease Control and Prevention

National Center of Viral and Rickettsial Diseases

National Center for Infectious Diseases

iii. Margaret Rennels, M. D.

Department of Pediatrics, University of Maryland

Her employers website states that she participated in virtually all phases of the testing of the licensed rotavirus vaccine[lxxix] Also, she is affiliated with U.S. Rotavirus Efficacy Group[lxxx]

iv. Richard Zimmerman, M.D.

American Academy of Family Physicians (AAFP)

The AAFP has conflicts with numerous vaccine manufacturers as described in this report.

v. Neal A. Halsey, M.D.

American Academy of Pediatrics

At the time of the rotavirus approval meeting, Dr. Halsey was seeking start-up funds from most of the vaccine manufacturers for the establishment of an institute for vaccine safety at Johns Hopkins University, where he works. He has already received \$50,000 from Merck and was awaiting funds from Wyeth Lederle. (Exhibit 56) He has received frequent reimbursements for travel expenses and honoraria from companies such as Merck.

Dr. Halsey Serves on the advisory board to the Immunization Action Coalition, an advocacy group funded by vaccine makers including: Aventis Pasteur, Chiron Corporation, Glaxo Wellcome, Merck & Co., Nabi, North American Vaccine, SmithKline-Beecham, Wyeth-Lederle Vaccines.[lxxxi]

vi. Peter Paradiso, Ph.D.

Lederle-Praxis Biologicals Division

Wyeth-Lederle Vaccines and pediatrics

vii. Florian Schodel, M.D.

Office for Clinical Vaccine Research

Merck Research Labs

7. ACIP is not Fairly Balanced in terms of the Points of View Represented

According to section 5 of FACA, membership on an advisory committee must be "fairly balanced in terms of points of view represented and the functions to be performed . . ." and the advice and recommendations of the advisory committee cannot be "inappropriately influenced by the appointing authority or by any special interest."

The absence of any consumer advocates on the ACIP has resulted in an advisory committee that is inherently not "fairly balanced." It is clear to the Committee that the intent of the FACA was for individuals who are affected by the work of the ACIP, in this case vaccine recipients, to have significant representation on the committee.

The ACIP's use of ex officio members, who are all government employees, in a voting capacity contradicts the notion of an advisory committee. Advisory committees are intended to provide independent information and advice to the government. In discussions with CDC staff, the Committee was informed that there are no records of an ex officio member ever voting no on an issue before the ACIP. This policy encourages a system where government officials make crucial

decisions affecting American children without the advice and consent of the governed.

Congress sought to eliminate "the danger of allowing special interest groups to exercise undue influence upon the Government through dominance of advisory committees which deal with matters in which they have vested interests." [lxxxii] However, the extensive use of working groups, in which conflict of interest procedures do not appear to be implemented, and the automatic waivers given to every advisory committee member, along with the absence of consumer representation, appear to thwart this goal.

Section VI Recommendations

As a result of the review of the ACIP and VRBAC practices, the following Committee has the following recommendations to the Department of Health and Human Services:

- 1. Individuals who serve on advisory committees involving vaccines should have no financial ties to vaccine manufacturers.***
- 2. Public participation on ACIP and VRBAC needs to be increased substantially.***
- 3. Conflict of Interest waivers should be used more stringently.***
- 4. A balance of policy perspectives should be incorporated into consideration of appointments of committee members.***
- 5. Any level of stock ownership in vaccine manufacturers should not be allowed by committee members.***
- 6. Department personnel need to insure that all documentation is fully and adequately completed.***
- 7. Full explanation of participation as expert witnesses in legal cases needs to be a part of financial disclosures.***
- 8. Individuals who have patents for vaccines for the same disease under discussion should not be allowed to participate in the discussion or vote of ACIP or VRBAC.***
- 9. Individuals who are developing vaccines for the same disease under discussion should be not be allowed to participate in the discussion or vote of ACIP and VRBAC.***
- 10. Working groups should be replaced by fully constituted Subcommittees on both the VRBAC and ACIP.***
- 11. Individuals should not be allowed to participate on two DHHS advisory committees at the same time.***
- 12. Individuals should not serve excessively long terms on a committee.***
- 13. The FDA should reconsider its policy on using temporary voting members.***
- 14. ACIP should not consider making a recommendation on a vaccine until it has been licensed by the FDA.***
- 15. CDC should follow the same policy in identifying affected companies for vaccine discussions as the FDA does and exclude participation of any individual who has a conflict.***

16. Organizations who send liaison members to participate in council meetings, should offer full disclosure of ties to the pharmaceutical industry.

17. The Department should review its policies and practices regarding conflicts of interest, participation on advisory committees, and terms of service, public participation, and balance of views and expertise.

[i] 5 U.S.C. app. II (1994).

[ii] Ensuring Coverage, Balance, Openness and Ethical Conduct for Advisory Committee Members Under the Federal Advisory Committee Act, 5 Admin. L.J. 231, Mary Kathryn Palladino, Spring, 1991.

[iii] 5 U.S.C. app. II '7(c). The guidelines for the Food and Drug Administration's advisory committee are set forth in 5 C.F.R. '2640 (1994)

[iv] 5 U.S.C. app. II '2(b)(6) (1994).

[v] 5 U.S.C., '10 (b).

[vi] 5 U.S.C., '5 (b)(2).

[vii] 5 U.S.C., '5(b)(3).

[viii] 18 U.S.C. "202-209.

[ix] 18 U.S.C. '208.

[x] 18 U.S.C. '208(b)(1).

[xi] 18 U.S.C. '208(b)(2).

[xii] 18 U.S.C. '208(b)(3).

[xiii] FACA amendments of 1989

[xiv] 5 C.F.R. '2640.103(a)(1).

[xv] 5 C.F.R. '2640.102(l).

[xvi] 5 C.F.R. '2640.102(m).

[xvii] 5 C.F.R. '2640.103(a)(3).

[xviii] Id.

[xix] Id. at (b).

[xx] Id. at (c)(5).

[xxi] 5 C.F.R. ' 2635.807.

[xxii] 5 C.F.R. '2635.502.

[xxiii] Minutes of ACIP meeting, October 22, 1999 at 51.

[xxiv] Bad Bug Book, U.S. Food & Drug Administration, Center for Food Safety & Applied Nutrition, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Chapter 33
<http://vm.cfsan.fda.gov/~mow/chap33.html>.

[xxv] Minutes of ACIP meeting, October 22, 1999, 56-57.

[xxvi] CDC's Rotavirus Q&A <http://www.cdc.gov/nip/Q&A/genqa/Rotavirus.htm>.

[xxvii] Rotashield Package Insert, Wyeth-Ayerst, 13.

[xxviii] VRBPAC charter, DHHS, 12/21/99.

[xxix] 5 C.F.R. '2640.103(a).

[xxx] Waiver Criteria Document 2000, FDA, 2. (Replacing the AWaiver Criteria Document (1994).@)

[xxxi] Id. at 19.

[xxxii] Id. at 23.

[xxxiii] Id. at 20. Where the grant or contract relates to the subject matter of the committee discussion, an actual conflict may arise. In situations where the grant or contract is unrelated to the product at issue, an appearance problem may arise. In either situation the conflict of interest may be waived and the member allowed to participate.

[xxxiv] Id. at 17.

[xxxv] Policy and Guidance, Handbook for FDA Advisory Committees, 12.

[xxxvi] Waiver Criteria Document (2000), FDA, 19.

[xxxvii] Id.

[xxxviii] VRBPAC "Rotashield" rotavirus vaccine approval meeting transcript, page 210, December 12, 1997.

[xxxix] A copy of the waiver forms have not been provided to the Committee.

[xl] The NIAID is the original developer of the Rotashield and other rotavirus vaccines. According to the FDA, as stated in Dr. Caroline Hall's Conflict of Interest Waiver form, Wyeth received the rights to further develop the Rotashield from NIAID and it is unknown which rotavirus vaccine was licensed to Wyeth by the NIAID.

[xli] Please see VRBPAC Charter. Exhibit 54

[xlii] See further discussion of the ACIP rotavirus working group in the ACIP section of this report. Section IV

[xlili] Consultants may be allowed to participate in the committee's discussion, but may not vote, unless designated a temporary voting member in advance of the meeting.

[xliv] According to the DHHS policy, members cannot serve for more than eight combined years within a period of 12 years.

[xlv] Letter from Mr. David Doleski, FDA, to the Government Reform Committee (March 30, 2000), stating that the DHHS policy states that Federal advisory committee members will not: ..serve on more than one committee within an agency at the same time.

[xlvi] Some of the frequent temporary members and consultants in the past few years include: Dr. Fleming (at least 4 meetings from 7/96 to 12/97); Dr. Karzon (at least 5 meetings between 4/96 until 9/99); Dr. Snider (at least 4 meetings in 1997, before becoming a standing member in 1998); Dr. Broome (8 meetings from 4/96 to 12/97); Dr. Diane Finkelstein (consultant in at least 5 meetings from 4/96 to 12/97, when she became a standing member); Dr. Theodore Eickhoff (consultant on at least 8 meetings from 4/96 to 9/99); Dr. Rob Breiman (4 meetings from 11/98 to 9/99).

[xlvii] For example, Dr. Ferrieri (at least 4 meetings past her appointment); Dr. Gregory Poland (at least 2 meetings past his appointment); Dr. Alison O'Brien (at least 3 meetings past her appointment) and Ms. Rebecca Cole (1 meeting past her appointment).

[xlviii] 42 C.F.R. §51b.204

[xlix] Section 1928 of the Social Security Act (42 U.S.C. § 1396s), as added by Section 13631 of the Omnibus Budget Reconciliation Act of 1993

[l] ACIP Charter, May 3, 1998 as approved by Claire Broome, Acting Director CDC (Exhibit 72)

[li] ACIP Charter, May 3, 1998 as approved by Claire Broome, Acting Director CDC, 2

[lii] ACIP Charter, May 3, 1998 as approved by Claire Broome, Acting Director CDC, 3

[liii] ACIP Charter, May 3, 1998 as approved by Claire Broome, Acting Director CDC, 2

[liv] The Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Policies and Procedures for Development of Recommendations for Vaccine Use and for the Vaccines for Children, January 2000, 4 (Exhibit 73)

[lv] ACIP Charter, May 3, 1998 as approved by Claire Broome, Acting Director CDC, 4

[lvi] The Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Policies and procedures for Development of Recommendations for Vaccine Use and for the Vaccines for Children, January 2000.

[lvii] Telephone interview of Dr. John Modlin (June 9, 2000).

[lviii] The Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Policies and Procedures for Development of Recommendations for Vaccine Use and for the Vaccines for Children, January 2000.

[lix] Interview of Dr. Dixie Snider, Mr. Kevin Malone and Mr. Joe Carter (June 1, 2000).

[lx] 5 C.F.R. § 2634.904(b).

[lxi] OGE Form 450: A review Guide, U.S. Office of Government Ethics, 15 (September 1996).

[lxii] OGE Form 450: A review Guide, U.S. Office of Government Ethics, 15 (September 1996).

[lxiii] Cited from a several examples of waivers provided by the CDC to the Government Reform Committee.

[lxiv] Interview of Dr. Dixie Snider, Mr. Kevin Malone and Mr. Joe Carter (June 1, 2000).

[lxv] Interview of Dr. Dixie Snider, Mr. Kevin Malone and Mr. Joe Carter (June 1, 2000).

[lxvi] ACIP Meeting June 24, 1998, 41.

[lxvii] ACIP Meeting, October 22, 1999.

[lxviii] Conflicts of Interest and the Disqualification of Federal Advisory Committee Members, Congressional Research Service Memorandum, June 6, 2000.

[lix] ACIP Meeting Minutes, February 11 and 12, 1998.

[lxx] Ethics Rules for Advisory Committee Members, for committee members appointed to serve on HHS advisory committees as SGEs, NIH Office of Federal Advisory Committee Policy (OFACP), 4, <http://www1.od.nih.gov/cmo/sge.htm>.

[lxxi] Interview of Dr. Dixie Snider, Mr. Kevin Malone and Mr. Joe Carter (June 1, 2000).

[lxxii] <http://www.aafp.org>.

[lxxiii] <http://www.aap.org>.

[lxxiv] <http://www.acog.org>; <http://www.figo2000.com/sponsors.cfm>.

[lxxv] <http://www.ama-assn.org>.

[lxxvi] http://www.idsociety.org/pd/grants_toc.htm.

[lxxvii] <http://www.bio.org>.

[lxxviii] Conflicts of Interest and the Disqualification of Federal Advisory Committee Members, Congressional Research Service Memorandum, June 6, 2000.

[lxxix] <http://som1.umaryland.edu/research.html>.

[lxxx] ACIP Meeting, February 13, 1997.

[lxxxi] <http://www.immunize.org/admin/funding.htm>.

[lxxxii] FAC Standards ACT, supra note 10, at 6, reprinted in FACA Source Book, supra note 2, at 276, citing Hearings on H.R. 4383 Before the Legal and Monetary Affairs Subcommittee. Of the House Comm. On Government Operations, 92 Cong., 2d Sess., at 13-55 (1971), reprinted in 1972 U.S. Code Cong. & Admin. News 3434-76.

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Exhibit SS



Weekly

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Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000

Each year, CDC's Advisory Committee on Immunization Practices (ACIP) reviews the recommended childhood immunization schedule to ensure it remains current with changes in manufacturers' vaccine formulations, revisions in recommendations for the use of licensed vaccines, and recommendations for newly licensed vaccines. This report presents the recommended childhood immunization schedule for 2000 ([Figure 1](#)) and explains the changes that have occurred since January 1999.

Since the publication of the immunization schedule in January 1999 (1), ACIP, the American Academy of Family Physicians, and the American Academy of Pediatrics have recommended removal of rotavirus vaccine from the schedule, endorsed an all-inactivated poliovirus vaccine (IPV) schedule for polio vaccination, recommended exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series, and added hepatitis A vaccine (Hep A) to the schedule to reflect its recommended use in selected geographic areas (2). Detailed recommendations for using vaccines are available from the manufacturers' package inserts, ACIP statements on specific vaccines, and the 1997 Red Book (3). ACIP statements for each recommended childhood vaccine can be viewed, downloaded, and printed at CDC's National Immunization Program World-Wide Web site, <http://www.cdc.gov/nip/publications/acip-list.htm>.

Removal of Rotavirus Vaccine from the Schedule

On October 22, 1999, ACIP recommended that Rotashield®* (rhesus rotavirus vaccine-tetravalent [RRV-TV]) (Wyeth Laboratories, Inc., Marietta, Pennsylvania), the only U.S. licensed rotavirus vaccine, no longer be used in the United States (4). The decision was based on the results of an expedited review of scientific data presented to ACIP by CDC. Data from the review indicated a strong association between RRV-TV and intussusception among infants 1-2 weeks following vaccination. Vaccine use was suspended in July pending the ACIP data review. Parents should be reassured that children who received the rotavirus vaccine before July are not at increased risk for intussusception now. The manufacturer withdrew the vaccine from the market in October.

Inactivated Poliovirus Vaccine for All Four Doses

As the global eradication of poliomyelitis continues, the risk for importation of wild-type poliovirus into the United States decreases dramatically. To eliminate the risk for vaccine-associated paralytic poliomyelitis (VAPP), an all-IPV schedule is recommended for routine childhood vaccination in the United States (5). All children should receive four doses of IPV: at age 2 months, age 4 months, between ages 6 and 18 months, and between ages 4 and 6 years. Oral poliovirus vaccine (OPV), if available, may be used only for the following special circumstances:

1. Mass vaccination campaigns to control outbreaks of paralytic polio.
2. Unvaccinated children who will be traveling within 4 weeks to areas where polio is endemic or epidemic.
3. Children of parents who do not accept the recommended number of vaccine injections; these children may receive OPV only for the third or fourth dose or both. In this situation, health-care providers should administer OPV only after discussing the risk for VAPP with parents or caregivers.

OPV supplies are expected to be very limited in the United States after inventories are depleted. ACIP reaffirms its support for the global eradication initiative and use of OPV as the vaccine of choice to eradicate polio where it is endemic.

Acellular Pertussis Vaccine

ACIP recommends exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series. The fourth dose may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at 15-18 months.

Hepatitis A

Hepatitis A vaccine (Hep A) is listed on the schedule for the first time because it is recommended for routine use in some states and regions. Its appearance on the schedule alerts providers to consult with their local public health authority to learn the current recommendations for hepatitis A vaccination in their community. Additional information on the use of Hep A can be found in recently published guidelines (2).

Hepatitis B

Special considerations apply in the selection of hepatitis B vaccine products for the dose administered at birth (6).

Vaccine Information Statements

The National Childhood Vaccine Injury Act requires that all health-care providers, whether public or private, give to parents or patients copies of Vaccine Information Statements before administering each dose of the vaccines listed in this schedule (except Hep A). Vaccine Information Statements, developed by CDC, can be obtained from state health departments and CDC's World-Wide Web site, <http://www.cdc.gov/nip/publications/VIS>. Instructions on use of the Vaccine Information Statements are available from CDC's website or the December 17, 1999, Federal Register (64 FR 70914).

References

1. CDC. Recommended childhood immunization schedule--United States, 1999. MMWR 1999;48:12-6.
2. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(no. RR-12).
3. American Academy of Pediatrics. Active and passive immunization. In: Peter G, ed. 1997 Red book: report of the Committee on Infectious Diseases. 24th ed. Elk Grove Village, Illinois: American Academy of Pediatrics 1997:1-71.
4. CDC. Withdrawal of rotavirus vaccine recommendation. MMWR 1999;48:1007.
5. CDC. Recommendations of the Advisory Committee on Immunization Practices: revised recommendations for routine poliomyelitis vaccination. MMWR 1999;48:590.
6. CDC. Recommendations regarding the use of vaccines that contain thimerosal as a preservative. MMWR 1999;48:996-8.

* Use of trade names and commercial sources is for identification only and does not constitute or imply endorsement by CDC or the U.S. Department of Health and Human Services.

Figure 1

FIGURE 1. Recommended childhood immunization schedule* — United States, January–December 2000

Vaccine	Age											
	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	24 mos	4–6 yrs	11–12 yrs	14–16 yrs
Hepatitis B [†]	Hep B		Hep B		Hep B			Hep B		Hep B		
Diphtheria and tetanus toxoids and pertussis [‡]		DTaP		DTaP	DTaP	DTaP		DTaP		DTaP	Td	
<i>H. influenzae</i> type b [§]		Hib	Hib	Hib	Hib		Hib		Hib		Hib	
Polio ^{**}		IPV		IPV		IPV			IPV		IPV	
Measles-mumps-rubella ^{††}		MMR		MMR		MMR			MMR		MMR	
Varicella ^{‡‡}		Var		Var		Var			Var		Var	
Hepatitis A ^{†††}		Hep A		Hep A		Hep A			Hep A		Hep A	

Range of recommended ages for vaccination.
 Vaccines to be given if previously recommended doses were missed or were given earlier than the recommended minimum age.
 Recommended in selected states and/or regions.

On October 22, 1999, the Advisory Committee on Immunization Practices (ACIP) recommended that Rotashield[®] (rhesus rotavirus vaccine-tetravalent [RRV-TV]), the only U.S.-licensed rotavirus vaccine, no longer be used in the United States (MMWR, Vol. 48, No. 43, November 5, 1999). Parents should be reassured that children who received rotavirus vaccine before July 1999 are not now at increased risk for intussusception.

* This schedule indicates the recommended ages for routine administration of licensed childhood vaccines as of November 1, 1999. Any dose not given at the recommended age should be given as a "catch-up" vaccination at any subsequent visit when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated. Providers should consult the manufacturers' package inserts for detailed recommendations.

[†] Infants born to hepatitis B surface antigen (HBsAg)-negative mothers should receive the first dose of hepatitis B vaccine (Hep B) by age 2 months. The second dose should be administered at least 1 month after the first dose. The third dose should be administered at least 4 months after the first dose and at least 2 months after the second dose, but not before age 6 months. Infants born to HBsAg-positive mothers should receive Hep B and 0.5 mL hepatitis B immune globulin (HBIG) within 12 hours of birth at separate sites. The second dose is recommended at age 1–2 months and the third dose at age 6 months. Infants born to mothers whose HBsAg status is unknown should receive Hep B within 12 hours of birth. Maternal blood should be drawn at delivery to determine the mother's HBsAg status; if the HBsAg test is positive, the infant should receive HBIG as soon as possible (no later than age 1 week). All children and adolescents (through age 18 years) who have not been vaccinated against hepatitis B may begin the series during any visit. Providers should make special efforts to vaccinate children who were born in or whose parents were born in areas of the world where hepatitis B virus infection is moderately or highly endemic.

[‡] The fourth dose of diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) can be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15–18 months. Tetanus and diphtheria toxoids (Td) is recommended at age 11–12 years if at least 5 years have elapsed since the last dose of diphtheria and tetanus toxoids and pertussis vaccine (DTP). DTaP or diphtheria and tetanus toxoids (DT). Subsequent routine Td boosters are recommended every 10 years.

[§] Three *Haemophilus influenzae* type b (Hib) conjugate vaccines are licensed for infant use. If Hib conjugate vaccine (PRP-OMP) (PedvaxHIB[®] or ComVax[®] [Merck]) is administered at ages 2 months and 4 months, a dose at age 6 months is not required. Because clinical studies in infants have demonstrated that using some combination products may induce a lower immune response to the Hib vaccine component, DTaP/Hib combination products should not be used for primary vaccination in infants at ages 2, 4, or 6 months unless approved by the Food and Drug Administration for these ages.

^{**} To eliminate the risk for vaccine-associated paralytic poliomyelitis (VAPP), an all-inactivated poliovirus vaccine (IPV) schedule is now recommended for routine childhood polio vaccination in the United States. All children should receive four doses of IPV, at age 2 months, age 4 months, between ages 6 and 18 months, and between ages 4 and 6 years. Oral poliovirus vaccine (OPV) (if available) may be used only for the following special circumstances: 1) mass vaccination campaigns to control outbreaks of paralytic polio; 2) unvaccinated children who will be traveling in <4 weeks to areas where polio is endemic or epidemic; and 3) children of parents who do not accept the recommended number of vaccine injections. Children of parents who do not accept the recommended number of vaccine injections may receive OPV only for the third or fourth dose or both. In this situation, health-care providers should administer OPV only after discussing the risk for VAPP with parents or caregivers. During the transition to an all-IPV schedule, recommendations for the use of remaining OPV supplies in physicians' offices and clinics have been issued by the American Academy of Pediatrics (Pediatrics, Vol. 104, No. 6, December 1999).

^{††} The second dose of measles, mumps, and rubella vaccine (MMR) is recommended routinely at age 4–6 years but may be administered during any visit, provided at least 4 weeks have elapsed since receipt of the first dose and that both doses are administered beginning at or after age 12 months. Those who previously have not received the second dose should complete the schedule no later than the routine visit to a health-care provider at age 11–12 years.

^{‡‡} Varicella (Var) vaccine is recommended at any visit on or after the first birthday for susceptible children, i.e., those who lack a reliable history of chickenpox (as judged by a health-care provider) and who have not been vaccinated. Susceptible persons aged >13 years should receive two doses given at least 4 weeks apart.

^{†††} Hepatitis A vaccine (Hep A) is recommended for use in selected states and regions. Information is available from local public health authorities and MMWR, Vol. 48, No. RR-12, October 1, 1999.

Use of trade names and commercial sources is for identification only and does not constitute or imply endorsement by CDC of the U.S. Department of Health and Human Services.

Source: Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), and American Academy of Pediatrics (AAP).

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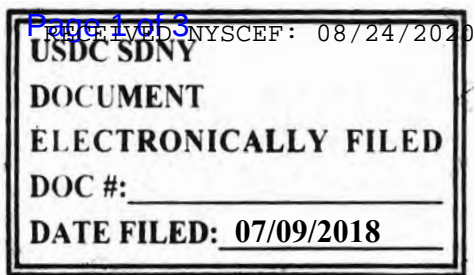
Morbidity and Mortality Weekly Report
Centers for Disease Control and Prevention
1600 Clifton Rd, MailStop E-90, Atlanta, GA 30333, U.S.A



Department of Health
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This page last reviewed 5/2/01

Exhibit TT



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Defendant.

STIPULATION

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines,"

provides as follows:

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

...

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network (“ICAN”) submitted a Freedom of Information Act request (the “FOIA Request”) to the Department of Health and Human Services (“HHS” or the “Department”), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary (“IOS”) maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

The [Department]’s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

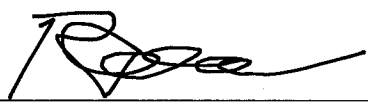
2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.


Dated: July 6, 2018
New York, New York

Dated: July 6, 2018
New York, New York


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SO ORDERED:


HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

Exhibit UU

ARTICLE

Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment

Charles W. LeBaron, MD; Judith Beeler, MD; Bradley J. Sullivan, PhD, MD; Bagher Forghani, PhD; Daoling Bi, MS; Carol Beck, BA; Susette Audet, BS; Paul Gargiullo, PhD

Objective: To evaluate the persistence of measles antibodies after 2 doses of measles vaccine in a setting where exposure to wild-type measles was unlikely. Measles was declared eliminated from the United States in 2000, an achievement attributed to effective implementation of a routine 2-dose vaccination policy. Some have questioned whether measles transmission could resume if immunity wanes in the absence of boosting from wild-type measles.

Design: Prospective, observational, volunteer cohort study.

Setting: Rural Wisconsin health maintenance organization.

Participants: Children who received the second measles vaccine dose at kindergarten (aged 4-6 years) or middle school (aged 10-12 years) in 1994 or 1995. Serum samples were collected periodically during a 10-year period for the kindergarten group and a 5-year period for the middle school group.

Intervention: Second dose of measles vaccine.

Main Outcome Measure: Measles antibody levels were assessed by plaque-reduction neutralization: titers less than 8 mIU/mL were considered seronegative and suggestive of susceptibility to measles, and titers of 120 mIU/mL or less were considered low and suggestive of potential susceptibility.

Results: During the study period, no measles was reported in the study area. Voluntary attrition reduced the study population from 621 at enrollment to 364 (58.6%) by study end. Before the second dose, 3.1% (19/621) had low titers, of whom 74% (14/19) were antibody-negative, with geometric mean titers being significantly higher in kindergarteners (1559 mIU/mL) than in middle schoolers (757 mIU/mL) and rates of negativity significantly lower (1.0% [3/312] vs 3.6% [11/309]). One month after the second dose, 0.2% (1/612) had low titers and none was seronegative, with geometric mean titers being significantly higher in kindergarteners (2814 mIU/mL) than in middle schoolers (1672 mIU/mL). By study end, 4.9% (18/364) had low titers and none was seronegative, with no significant difference in geometric mean titers between kindergarteners (641 mIU/mL) and middle schoolers (737 mIU/mL) when both groups were aged 15 years. Projections suggest that the proportion of persons with low antibody levels may increase over time.

Conclusions: Measles antibody persisted in all vaccinees available for follow-up 10 years after a second dose of vaccine, with no seronegative results detected. Declining titers suggest the need for vigilance in ensuring disease protection for the vaccinated population.

Arch Pediatr Adolesc Med. 2007;161:294-301

Author Affiliations: Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Ga (Drs LeBaron and Gargiullo and Ms Bi); Division of Viral Products, US Food and Drug Administration, Bethesda, Md (Dr Beeler and Ms Audet); Marshfield Clinic Medical Research Foundation, Marshfield, Wis (Dr Sullivan and Ms Beck); Viral and Rickettsial Disease Laboratory Branch, Division of Communicable Disease Control, California Department of Health Services, Richmond (Dr Forghani).

BEFORE LICENSURE OF MEASLES vaccine in 1963, approximately 4 million cases, 50 000 hospitalizations, and 500 deaths due to measles occurred annually in the United States.¹ Within 20 years of vaccine introduction, measles incidence had been reduced by 99%, but transmission continued, particularly among schoolchildren who had received only 1 dose of vaccine.¹ In 1989, facing a nationwide measles resurgence, the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics recommended that schoolchildren receive a second dose of measles-mumps-rubella vaccine (MMR) to provide protection to those who had an inadequate response to the first dose.^{2,3} Since

then, the number of MMR doses administered annually has been enough to provide 2 doses to each child in the US birth cohort, plus catch-up doses to 4 million others.⁴ By 1993, viral transmission was interrupted⁵ and, by 2000, measles was declared eliminated in the United States,⁶ a historic achievement attributed to effective implementation of a routine 2-dose measles vaccination policy.⁷

Childhood vaccination levels remain high,⁸ but imported disease remains a threat because approximately 40 million measles cases occur globally each year.⁹ Many studies have suggested that vaccine-induced immunity is persistent, perhaps even lifelong, but most were performed in an era when boosting from wild-type virus was common.¹⁰⁻¹⁴ Some investigators

Table 1. Study Design and Subject Retention

Age, y	MMR2 in Kindergarten				MMR2 in Middle School				
	Serum No.	Time From MMR2	Year Span	Subjects, No. (%) [*]	Serum No.	Time From MMR2	Year Span	Subjects, No. (%) [*]	
5	1	Before	1994-1995	312 (100.0)	1	Before	1994-1995	309 (100.0)	
	2	1 mo	1994-1995	304 (97.4)		2	1 mo	1994-1995	308 (99.7)
	3	6 mo	1994-1995	302 (96.8)		3	6 mo	1994-1995	306 (99.0)
7	4	2 y	1996-1997	243 (77.9)		4	2 y	1996-1997	266 (86.1)
	5	5 y	1999-2000	174 (55.8)		5	5 y	1999-2000	210 (68.0)
12	6	7 y	2001-2002	161 (51.6)					
15	7	10 y	2004-2005	154 (49.4)					

Abbreviation: MMR2, second dose of measles-mumps-rubella vaccine.

^{*}Percentage of originally enrolled cohort.

have raised concerns that, in the absence of such boosting, waning immunity may produce a population of susceptible persons sufficient to sustain renewed measles transmission.¹⁵⁻²¹ Because measles tends to be more severe clinically among adults,¹⁰ progressive waning immunity might have important clinical and public health consequences.

In 1994, the Centers for Disease Control and Prevention began a longitudinal study of the persistence of measles antibody levels comparing 2 different measles second-dose vaccination schedules. At the time, based on then-divergent ACIP and American Academy of Pediatrics recommendations,^{2,3} some states had passed laws requiring the second dose for kindergarten entry and others for middle school entry, although ultimately all required it for school entry at some age. Subsequently, ACIP and the American Academy of Pediatrics agreed on a kindergarten recommendation,^{22,23} but many states continued with their original legal requirements. We report the findings of this longitudinal study.

METHODS

The study was conducted to evaluate short- and long-term antibody response after a second dose of MMR vaccine (MMR2) in a setting where exposure to wild-type measles was unlikely, and to compare schedules in which MMR2 was administered at kindergarten vs middle school entry. We hypothesized that measles antibody levels would not be significantly lower at high school age for children who received the second dose of vaccine in kindergarten than for those who received it in middle school.

STUDY PARTICIPANTS

The study population was drawn from patients of Marshfield Clinic, the principal health care provider for a rural area of Wisconsin with a low incidence of reported measles. The clinic has a longitudinally stable patient population with a low rate of utilization of outside care.

The state of Wisconsin had enacted a law in 1990 requiring MMR2 for children entering kindergarten and middle school. The computerized files of Marshfield Clinic were reviewed to identify 2 groups of MMR2-eligible children: those in kinder-

garten (4-6 years old) and those in middle school (10-12 years old). Families were contacted and information was obtained about the mother's date of birth, child's date of birth, documented dates of all vaccinations, sex, race-ethnicity as declared by the family, history of measles-mumps-rubella disease or exposure, and current state of health. The date of the first administration of MMR (MMR1) was verified by provider record check, and children who did not receive MMR1 between 12 and 24 months of age were excluded. Candidate study subjects were also excluded if they had (1) previously had either measles, mumps, or rubella, since different parts of the study evaluated immune response to each antigen; (2) lived in the same household with anyone who had had these diseases during the subject's lifetime; (3) previously received any component of MMR vaccine other than as specified herein; (4) received any other vaccinations within 30 days before the scheduled date of MMR2 administration; (5) any contraindication to MMR vaccination according to ACIP recommendations²²; or (6) any condition likely to impair immune response to MMR vaccine according to ACIP recommendations.²² Parents of study subjects were provided with informed permission materials, and middle schoolchildren were additionally provided with informed assent materials. The study was approved by the Human Subjects Protection offices of Marshfield Clinic, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

STUDY DESIGN AND METHODS

Serum samples were obtained from enrolled children, and the second dose (M-M-R II; Merck & Co Inc, Whitehouse Station, NJ) was administered less than 72 hours thereafter, along with any other vaccines for which the child was eligible. Adverse events in the month after vaccination were examined, as previously reported.²⁴ Postvaccination serum samples were drawn at intervals permitting comparisons of the 2 groups at similar ages (**Table 1**). At each specimen collection, families were questioned concerning measles exposures, vaccinations, and other health events.

Measles antibody levels were evaluated by means of the plaque-reduction neutralization (PRN) test, as previously described.²⁵ Fourfold serial dilutions of serum were tested in duplicate starting at 1:8 and ending at 1:8192 and run in parallel with the Second World Health Organization International Standard Reference Serum (66/202). Serum samples with reciprocal titers of less than 8 or greater than 8192 were assigned values of 4 and 16 400, respectively. Geometric mean titers were

Table 2. Study Population Characteristics

Characteristic	Group	
	Kindergarten (n = 312)	Middle School (n = 309)
Sex, No. (%) F	153 (49.0)	150 (48.5)
Race/ethnicity, No. (%) non-Hispanic white	305 (97.8)	307 (99.4)
Mother's birth year, median (range)*†	1961 (1946-1972)	1957 (1940-1967)
Age at MMR1, median (range), mo	15.6 (12.8-24.7)	15.7 (14.1-24.5)
Time between MMR1 and MMR2, median (range), y†	3.7 (2.4-4.8)	9.8 (8.4-11.2)
Age at MMR2, median (range), y†	5.1 (4.2-6.1)	11.2 (10.1-12.5)
Receipt of other immunizations with MMR2, No. (%)†	222 (71.2)	1 (0.3)

Abbreviations: MMR1 and MMR2, first and second doses of measles-mumps-rubella vaccine, respectively.

*Birth year of biological mother could not be ascertained for 15 children (5 in the kindergarten group and 10 in the middle school group) who lived with other persons.

†Differences between the kindergarten and middle school groups were significant at $P < .001$ for 4 characteristics (mother's birth year, time between MMR1 and MMR2, age at MMR2, and receipt of other immunizations with MMR2). Differences were not significant at $P < .05$ for other characteristics (sex, race, and age at MMR1).

calculated as log-transformed reciprocal neutralizing antibody titers and reported as back-transformed titers standardized against the Second World Health Organization reference serum, with 1:8 corresponding to 8 mIU/mL. To ensure comparability of results for assays performed during the 10-year course of the study, an assay was considered valid only if the end point titer measured for the World Health Organization reference serum did not vary by more than 20% from the assigned titer of 1:5000. Each serum drawn 1 month after MMR2 administration was also evaluated for anti-measles IgM by enzyme immunoassay, as previously described.²⁶ Serum samples with an optical density index of 1.0 or greater were considered positive; those at 0.5 to 0.9 were considered indeterminate.

On the basis of studies comparing preexisting PRN titers with subsequent measles attack rates,^{27,28} serum samples were assigned to 1 of 4 categories of antibody level: (1) negative (<8 mIU/mL), susceptible to infection and disease; (2) low (8-120 mIU/mL), potentially susceptible to infection and disease; (3) medium (121-900 mIU/mL), potentially susceptible to infection but not to disease; and (4) high (>900 mIU/mL), not susceptible to infection or disease. Serum samples were also dichotomized as potentially susceptible (≤ 120 mIU/mL) and not susceptible (>120 mIU/mL). The following potential risk factors for antibody levels were examined: sex, mother's birth year, age at MMR1, time between MMR1 and MMR2, receipt of other vaccinations with MMR2, and (for post-MMR2 serum samples) pre-MMR2 titer levels.

STATISTICAL AND MODELING METHODS

To detect a difference in potential susceptibility of 5% vs 15% between the 2 study groups, with 80% power and 95% confidence intervals, a sample size of 300 was estimated. Assuming 50% attrition during the 10-year study, an enrollment goal of 600 was set. To evaluate the potential impact of attrition on study findings, we compared risk factor characteristics and antibody levels for those initially enrolled with those of the subset who completed the study. In bivariate comparisons, the Pearson χ^2 test was used for categorical variables, the row-mean-scores/Cochran-Mantel-Hansel test for ordinal variables, and the Wilcoxon rank sum for continuous variables. For testing the association between continuous variables, multiple linear regression was used.

To estimate future antibody trends, we restricted analysis to the kindergarten group, for whom we had 10 years' data and whose dosing schedule followed current US policy. We deter-

mined the 25th percentile, median, and 75th percentile of titers for each serum collection, then fitted linear regression models to the natural logs of these quantiles, and projected future values of these percentiles. A linear regression model was also fitted to the raw scatter of log_e titers to predict the mean log_e titer beyond the last collection. The predicted mean log_e titers and mean squared error estimated from this model were used as means and variances, respectively, of normal distributions for projecting the future proportions of the cohort with low and negative titers. This model was previously used by Woolhouse et al²⁹ for examining vaccination-induced protection against foot-and-mouth disease. Because no postvaccination neutralizing titers were below the limit of detection in our study, it was not necessary to use the more complicated mixture model described by Moulton and Halsey³⁰ for regression analysis of antibody response to measles vaccine or that used by Mossong et al^{18,31} for projecting future measles PRN titers of 120 mIU/mL or less in the absence of wild-type measles boosting, both of which take into account censored observations arising from the lower limit of antibody assays. Confidence intervals around our predicted proportions of the population with lower than protective antibody titers were obtained by standard statistical methods. As an internal check, we examined how closely the model's "back-estimate" of the prevaccination antibody levels of the middle schoolers when they were in kindergarten approximated the measured prevaccination levels of the kindergarten study group: the predicted geometric mean titer (1626 mIU/mL) differed by 4% from the measured geometric mean titer (1559 mIU/mL).

RESULTS

A total of 621 children were enrolled, of whom 608 (97.9%) provided serum samples through the first 3 collections (Table 1). Thereafter, attrition reduced the study population to 364 (58.6%) by the final collection. Overall and within each group, the 364 children who completed the study did not differ significantly from the initially enrolled 621 for available titers or any risk characteristic.

Reflecting the rural Midwestern source population, 98.6% (612/621) of the overall study population was non-Hispanic white (Table 2), with no significant difference between the groups. Middle schoolers' mothers

were born significantly earlier than kindergarteners'. Specifically more were born before 1957 (presumed immune from wild-type virus under US policy²²): 43.8% (131/299) vs 14.3% (44/307); $P < .001$. Per study protocol, all children received MMR1 between 12 and 24 months of age, most within 60 days of 15 months of age, with no significant difference between groups.

POTENTIAL MEASLES EXPOSURES

The 7 counties surrounding the clinic (2000 population, 364 187)³² reported 41 confirmed cases of measles to the Centers for Disease Control and Prevention from 1985 (the first year for which county-specific data are available) until the start of the study in 1994. Subjects' birth years ranged from 1981 to 1991, so local exposure to measles was possible before the study start, although none was reported by study families. During the study period (1994-2005), no measles cases were reported in the 7 counties, and no family reported measles exposure. According to clinic records, no study subject was diagnosed as having measles or received additional measles vaccinations from birth through 2005. To assess the extent to which unreported measles exposures may have occurred among the study population, we looked for 4-fold titer increases in drawn serum samples starting 6 months after MMR2 through the end of the study. Among 1208 serum pairs, one 4-fold rise was detected. The child's family denied any exposure to measles, foreign travel, or repeat measles vaccinations.

TITERS BEFORE AND AFTER MMR2

Before the second dose, the majority of both groups had high titers, and the proportion of potential susceptible individuals was small (3.1% [19/621]), but 74% (14/19) of these were antibody-negative (**Figure 1**). Compared with middle schoolers, kindergarteners had higher titers (geometric mean titer, 1559 vs 757 mIU/mL; $P < .001$), fewer potentially susceptible individuals (1.0% [3/312] vs 4.9% [15/309]; $P = .002$), and fewer negative samples (1.0% [3/312] vs 3.6% [11/309]; $P = .03$).

One month after MMR2, titers significantly increased for each study group, but beyond 6 months titers were not significantly different from pre-MMR2 levels (**Figure 1**). Similarly, a 4-fold rise in titers was observed for 11.6% (71/612) of the study population 1 month after MMR2, but this declined to 3.6% (22/608) by 6 months and 1.3% (2/154) by 10 years. All 14 children who were seronegative (< 8 mIU/mL) before MMR2 maintained titers greater than 120 mIU/mL at every post-MMR2 serum collection. Of these, 6 (43%) had positive and 5 (36%) had indeterminate IgM responses. Titers for the 5 children with low prevaccination antibody levels (8-120 mIU/mL) increased less than did titers for the 14 children who were seronegative (range of 6-month titers, 104-323 vs 427-16 400 mIU/mL), but all 5 achieved titers greater than 120 mIU/mL at their last serum collection. None of the 5 had a positive or indeterminate IgM response. For the 602 children who had medium or high antibody levels before MMR2, titers increased significantly at 1 month but returned to pre-MMR2 levels

by 6 months, at which point only 1.0% (6/583) had titers 4-fold higher than at baseline. Of these 602 children, 1 (0.2%) had a positive IgM response and 4 (0.7%) had an indeterminate response. Kindergarteners had significantly higher titers than middle schoolers both 1 month and 6 months after MMR2.

Of 2428 post-MMR2 specimens tested, 32 (1.32%) showed potential susceptibility (≤ 120 mIU/mL), but none was negative (< 8 mIU/mL). Titers fell significantly over time for the study population overall and, by the final collection, 4.7% (18/382) of children were potentially susceptible, not significantly different from the pre-MMR2 proportion (3.1% [19/621]), though none was negative. Of those who were potentially susceptible at the last serum collection, none had been potentially susceptible before MMR2. At each serum collection, kindergarteners maintained significantly higher titers than middle schoolers but, at equivalent post-MMR2 ages (12 and 15 years), antibody levels and rates of susceptibility were not significantly different between the groups.

RISK FACTORS FOR MEASLES ANTIBODY LEVELS

For pre-MMR2 titers, shorter time since MMR1 was the only factor significantly associated with higher titers ($R^2 = 0.09$, $P < .001$). Although explaining less than 10% of titer variability, this factor was sufficient to explain the higher titers in kindergarteners than middle schoolers. For each post-MMR2 titer, the dominant factor was higher pre-MMR2 titers ($R^2 = 0.215-0.318$, $P < .001$) (**Figure 2**). Of the 18 children who were potentially susceptible on the final serum collection, 13 (72%) had been in the lowest quartile of titers before MMR2. With each successive collection, length of time since MMR1 played a diminishing role in post-MMR2 antibody levels, ultimately adding only about 0.1% to the value of a multivariate linear regression model. No other evaluated factor played a significant role in post-MMR2 antibody levels.

PROJECTED ANTIBODY LEVELS

Projection of future antibody levels in the kindergarten group suggested a continued slow decline in titers, with an increase in the proportion potentially susceptible (≤ 120 mIU/mL) reaching 33% by 20 years after MMR2 (**Figure 3**). However, the proportion seronegative (< 8 mIU/mL) was not projected to reach 1% until 30 years after MMR2.

COMMENT

In summary, we found that, in a population of children who had received 2 doses of measles vaccine at ages and intervals consistent with US policy and who were unlikely to have been exposed to wild-type measles, potential susceptibility rates were low for as long as 10 years after the second dose. These findings are consistent with low rates of 2-dose vaccine failure during US outbreaks³³⁻³⁵ and cross-sectional serosurveys indicating high rates of immunity across multiple US age strata.³⁶ How-

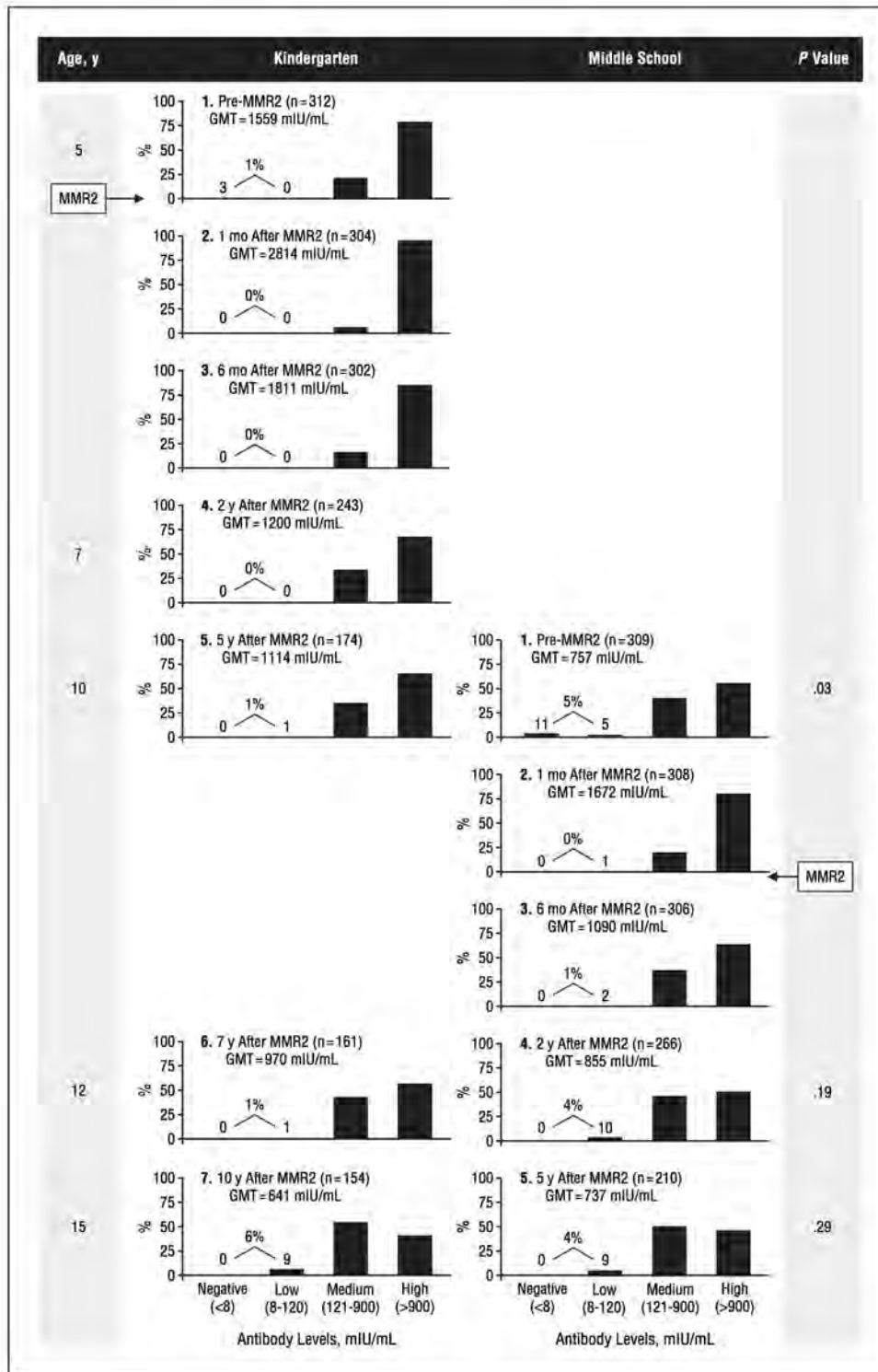


Figure 1. Changing distribution of antibody levels. Numerals above bars for the 2 lower antibody categories (negative and low) indicate the number of children in each category; the percentage above these numerals represents the proportion potentially susceptible (titers, ≤ 120 mIU/mL). The boldface numeral in the top left corner of each graph represents the serum collection; MMR2, second measles-mumps-rubella vaccination; n, the population providing serum samples at that collection; and GMT, geometric mean titer for that collection. P values are from the Wilcoxon rank sum test indicating the difference between the 2 groups in antibody titers at equivalent ages.

ever, the progressive decline in antibody levels suggests the need for continued vigilance in ensuring disease protection for the vaccinated population.

Two prospective studies^{27,28} have examined the relationship between low PRN titers and risk of measles disease. On a US college campus where a blood drive had occurred before a measles outbreak, 7 of 8 students with PRN titers of 16 to 120 mIU/mL acquired measles, compared with 0 of 71 with titers greater than 120 mIU/mL.²⁷ Dur-

ing a vaccine trial in Senegal, 13 of 36 children with titers of 40 to 125 mIU/mL acquired measles, compared with 7 of 258 of those with titers greater than 125 mIU/mL.²⁸ These studies suggest that low antibody levels may not be protective against measles disease, and the 120-mIU/mL threshold of potential susceptibility used in our study has been used in previous studies modeling projections of vaccine-induced immunity in the absence of wild-type measles boosting.¹⁸

A rise in the proportion of persons with low antibody levels suggests an increase in potential susceptibility, but low titers are unlikely to represent the same risk of illness or viral transmission as absent antibodies.^{28,37-39} In our study, none of the children with low titers had positive or even indeterminate IgM responses to MMR2, in contrast to the majority of those with negative titers, suggesting that those with low titers may generate an anamnestic response to wild-type virus, consistent with previous studies.³⁷⁻³⁹ If ongoing viral transmission requires that a substantial portion of the population be antibody-negative, our data suggest that such a situation may be several decades away. Furthermore, as demonstrated by Ward et al³⁷ and Gans et al,^{40,41} cell-mediated immunity plays an important role in resistance to measles infection, an issue we did not address. This is an area in which large-scale prospective studies are needed to provide reliable and quantifiable population-based indicators of cell-mediated protection from measles disease. Such studies would assist clinicians and public health policymakers to determine the relative importance of measles-specific T cells to protection as they encounter an expanding number of persons with low, indeterminate, or undetectable measles antibody levels.

In our study, intrinsic regulatory processes appeared to play an important role in maintenance of specific antibody levels. Persons with starting antibody levels higher than those of their peers tended to be boosted higher and stay higher over time. These data imply a preferred steady state of antibody production for each individual, findings consistent with those of St Sauver et al⁴² and Poland and colleagues⁴³ demonstrating an important role for genetic factors in measles immunity.

For both study groups, MMR2 immediately increased titers and virtually eliminated potential susceptibility. Although the titer increase lasted no longer than 6 months, rates of potential susceptibility did not return to prevaccination levels until 5 to 10 years later, and children with negative antibody levels were not detected at study end. At each collection, kindergarteners tended to have higher titers than middle schoolers but, for equivalent post-MMR2 ages, antibody levels were not significantly different. While these data do not suggest a dramatic advantage for either dosing schedule in the high school years, those who received the second dose at kindergarten were protected through the primary school years.

Our findings should be interpreted cautiously. Study subjects were not representative of the US childhood population: all came from a rural environment, almost all were non-Hispanic white, all were in good health, and all received MMR doses at recommended ages. Immunocompromised and other children who might not receive, or respond to, MMR were excluded from our study, and these children may form a growing and important group of susceptible individuals in the future. Attrition reduced the kindergarten group by more than half and the middle school group by almost a third. Our categorization of antibody levels is based primarily on 2 studies. We did not assess cellular-mediated responses to measles virus, and low titers are not necessarily equivalent to lack of immunity.

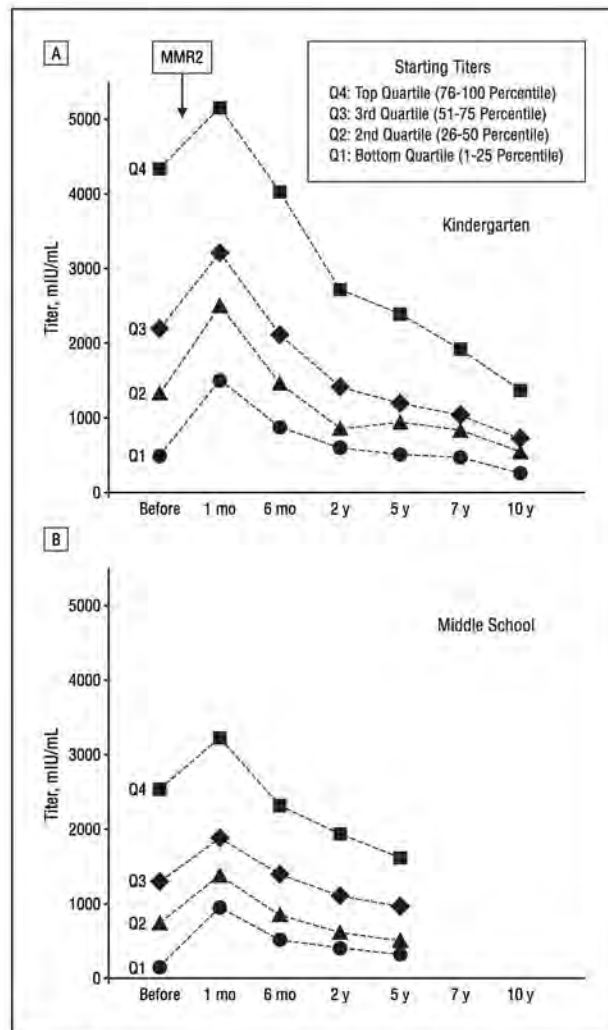


Figure 2. Serial antibody levels by starting titer in the kindergarten group (A) and the middle school group (B). Serum collections on the x-axis are not corrected for time scale. The population was divided into 4 cohorts based on quartile (Q) of antibody level before second measles-mumps-rubella vaccination (MMR2). Lines represent geometric mean titers for each cohort at each serum collection.

Projecting antibody levels decades into the future is an inherently speculative enterprise, in which small changes in slope can result in large alterations in predicted titers. In the absence of antigenic stimulation, titers can be expected to decline, but the rate of decline may flatten out, producing a steady state of long-term protection rather than an increasing number of susceptible individuals. To date, 2-dose failure has been relatively rare in US outbreaks, most which have been associated with 1-dose failure or failure to vaccinate.³³⁻³⁵ However, because elimination of indigenous measles was only declared in 2000, it may be some time before the majority of the US population has measles immunity that is attributable to vaccine alone. The resurgence of pertussis among teenagers and young adults requiring addition of an adolescent booster dose⁴⁴ and recent outbreaks of mumps among college students who had received 2 doses of MMR⁴⁵ suggest that it may be risky to discount the potential threat of diseases that appear on the verge of extinction because of high vaccination levels among toddlers.

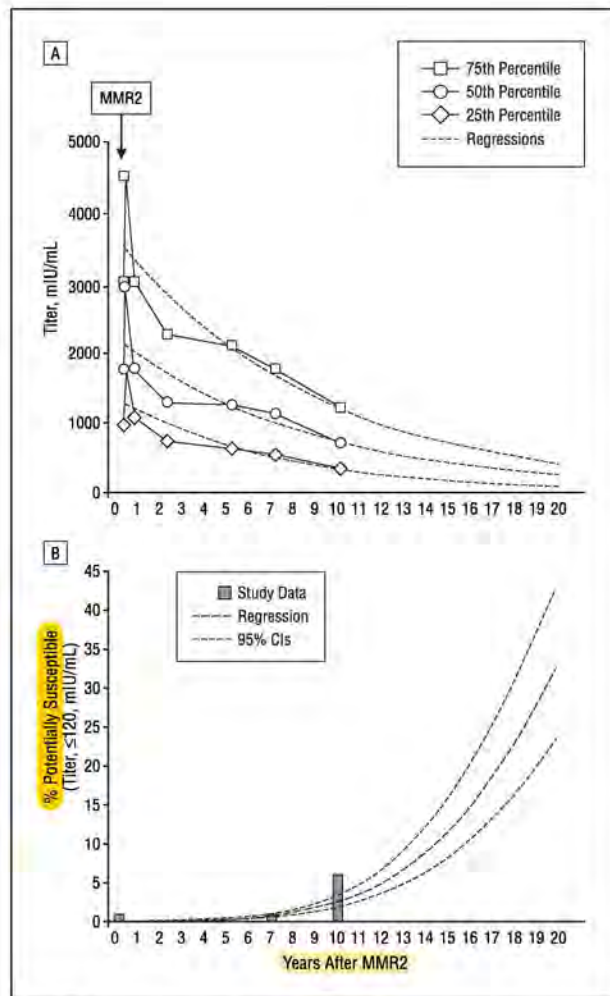


Figure 3. Projected antibody levels. A, Titers in the kindergarten group. B, Percentage potentially susceptible in the kindergarten group. The percentage seronegative (titer, < 8 mIU/mL) is not shown because it was predicted to be less than 1% through 20 years after second measles-mumps-rubella vaccination (MMR2). CI indicates confidence interval.

We believe our study demonstrates that the US routine 2-dose measles vaccination strategy can produce high rates of seropositivity that persist for as long as 10 years after the second dose, even in the absence of wild-type virus boosting. Nonetheless, cessation of disease transmission can produce complacency. Maintenance of measles elimination will require continued high rates of 2-dose vaccination,^{7,46} vigilance in monitoring population-based immunity levels,⁴⁷ and reduction in the risk of imported disease through support to other nations in their efforts to control or eliminate measles.⁴⁸

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The oldest medical text extant anywhere is a cuneiform tablet from Mesopotamia. The most ancient known Egyptian medical writings date from a later period, but they refer back to texts far older. Most important among the more ancient treatises were: *Book on the Vessels of the Heart*; *The Physician's Secret: Knowledge of the Movement of the Heart and Knowledge of the Heart*; and *Collection on the Expelling of the Wehedu* (a toxic principle in the body).

—From *Medicine: An Illustrated History* by Albert S. Lyons, MD, and R. Joseph Petrucelli, MD, 1987

Exhibit VV

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MEASLES VIRUS INFECTION WITHOUT RASH IN CHILDHOOD IS RELATED TO DISEASE IN ADULT LIFE

Tove RnnePublished: January 05, 1985 • DOI: [https://doi.org/10.1016/S0140-6736\(85\)90961-4](https://doi.org/10.1016/S0140-6736(85)90961-4)



Abstract

The presence of measles specific antibodies is usually taken as evidence of typical measles in the past; in the present study it was regarded as evidence of infection with measles virus, but not necessarily of the common disease accompanied by a typical rash. The association between a negative history of measles in childhood and certain diseases later in life was investigated by a historical prospective method, based on school health records combined with self-reporting in adulthood, and tests for specific IgG measles antibody. There was evidence of association between a negative history of measles, exposure in early life (possibly injection of immune serum globulin after exposure), and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumours. It is suggested that the presence of measles virus specific antibodies at the time of acute infection interferes with development of specific cytolytic reactions, and enables intracellular measles virus to survive the acute infection. If this hypothesis is verified, use of immune serum globulin after measles exposure has to be reconsidered.

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Exhibit WW

The Vaccine Adverse Event Reporting System (VAERS) Results

Event Category	Year Vaccinated	Events Reported	Percent (of 1,103)
Hospitalized	2013	268	24.30%
	Total	268	24.30%
Emergency Room / Office Visit **	2013	988	89.57%
	Total	988	89.57%
Total		1,256	113.87%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

**** These value are only available from VAERS-1 Report Form, active 07/01/1990 to 06/29/2017.**

Notes:

Caveats:

DISCLAIMER: VAERS staff at CDC and the Food and Drug Administration (FDA) follow up on all serious adverse event reports to obtain additional medical, laboratory, and/or autopsy records to help understand the circumstances. However, VAERS public data do not generally change based on the information obtained during the follow-up process. There are limitations to VAERS data. A report to VAERS does not mean that the vaccine caused the adverse event, only that the adverse event occurred sometime after vaccination. Read more about interpreting VAERS data: [More information.](#)

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. [More information.](#)

Data contains VAERS reports processed as of 2/14/2019. The VAERS data in WONDER are updated monthly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. [More information.](#)

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was available only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

Help: See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

Query Date: Apr 3, 2019 10:32:00 AM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - last month, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Apr 3, 2019 10:32:00 AM

Query Criteria:

- Date Report Received:** Jan., 2000 to Dec., 2018
- Date Vaccinated:** Jan., 2013 to Dec., 2013
- Event Category:** Hospitalized; Emergency Room / Office Visit **
- Vaccine Products:** MEASLES AND MUMPS VIRUS VACCINE, LIVE (MM); MEASLES AND RUBELLA VACCINE (MER); MEASLES VACCINE (MEA); MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE (MMR); MEASLES, MUMPS, RUBELLA, AND VARICELLA VACCINE (PROQUAD) (MMRV)
- Group By:** Event Category; Year Vaccinated
- Show Totals:** True
- Show Zero Values:** False

Grant Final Report

Grant ID: R18 HS 017045

**Electronic Support for Public Health–Vaccine Adverse
Event Reporting System (ESP:VAERS)**

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:

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Michael Klompas, MD, MPH

Performing Organization:

Harvard Pilgrim Health Care, Inc.

Project Officer:

Steve Bernstein

Submitted to:

The Agency for Healthcare Research and Quality (AHRQ)

U.S. Department of Health and Human Services

540 Gaither Road

Rockville, MD 20850

www.ahrq.gov

Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

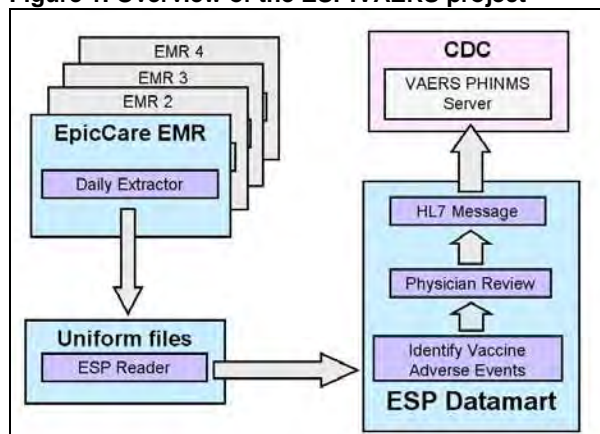
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect*. A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data*.

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center <http://esphhealth.org>, specifically, the Subversion repository available at: <http://esphhealth.org/trac/ESP/wiki/ESPVAERS>.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of “problem” drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians’ usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atrius currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atrius physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atrius was included in our adverse event surveillance system (ESP:VAERS). Atrius serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atrius is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atrius population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: <http://esphealth.org>.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

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Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Exhibit XX



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Original article

Spontaneous improvement of intractable epileptic seizures following acute viral infections

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Abstract

In general, epileptic seizures become more serious following infections. However, transient and permanent improvement of epileptic seizures has been observed following acute viral infections, without a recent change in anti-epileptic therapy. Questionnaires were sent to 73 institutions, throughout Japan, where pediatric neurologists care for children with epilepsy to characterize this phenomenon through clinician survey. Completed surveys were received from 11 institutions, and 21 cases were selected for the study. The age of the patients were 6 months to 17 years. The West syndrome or epilepsy subsequent to West syndrome cases were 16 out of 21. Two cases of symptomatic generalized epilepsy and one case each of symptomatic partial epilepsy, continuous spike-waves of slow sleep and severe myoclonic epilepsy in infancy were also reported. **These seizures disappeared within 2 weeks subsequent to viral infections such as, exanthema subitum, rotavirus colitis, measles and mumps.** The disappearance of intractable epileptic seizures following acute viral infections might be related to the inflammatory processes or the increased levels of antibodies after viral infections.

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Keywords: Spontaneous improvement; Acute viral infection; Intractable epilepsy

1. Introduction

Epileptic seizures generally become more serious following infections. However, it is well known that in rare instances, epileptic seizures, mostly seizures in West syndrome disappear or decrease in severity after acute viral infections without changes to anti-epileptic medications. This evidence has prompted us to analyze clinical data of this phenomenon through a multi-center survey throughout Japan. The goal of our study was to better characterize this phenomenon through clinician survey.

2. Subjects and methods

Questionnaires were sent to Pediatric neurologists in 73 university hospitals, children's hospitals, and epilepsy centers in Japan. The questionnaires reported: the type of epilepsy or epileptic syndrome according to the international classification of the ILEA, 1989; the infectious disease that the patient experienced; the start of seizure remission in relation to the start of the illness; the duration of remission; any changes in the EEG during the disappearance of seizures; any changes in the serum concentrations of anti-epileptic drugs during the disappearance of seizures; any additional medications given for the illness; recurrence of seizures; and the suspected reasons for the disappearance of seizures.

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3. Results

Completed surveys were received from 11 institutions, and 21 cases were selected for this study based on the criteria. The criteria fulfilled the conditions in which patient's frequent seizures had disappeared for at least 1 month after viral infections without changes to anti-epileptic therapy. The age of patients ranged from 6 months to 17 years. The West syndrome or epilepsy subsequent to West syndrome was diagnosed for 16 out of 21 cases. Two cases were symptomatic generalized epilepsy. Symptomatic partial epilepsy, continuous spike-waves of slow sleep (CSWS), and severe myoclonic epilepsy in infancy (SMEI) were reported concurrently in another case. Thirteen patients with either West syndrome or epilepsy subsequent to West syndrome were symptomatic, and three patients were cryptogenic in etiology. The patient's international classification of epilepsy or epileptic syndromes are presented in Table 1. The preceding infections were four cases of exanthema subitum, four cases of rotavirus gastroenteritis, three cases of measles, three cases of upper respiratory infections, one case of mumps and cytomegalovirus infection, and five cases of probable common cold. The type of infectious disease encountered was listed in Table 2. Seizures disappeared an average of 4.5 days, (with a range of 1–14 days) after the onset of infection. In four patients with West syndrome and in one patient with CSWS, the seizures did not recur. The mean duration of follow-up was 34 months with a range from 3 months to 4 years. In 13 patients, the seizures recurred. In these patients, the duration of remission had a median of 7 months and a range from 1 to 30 months. During the remission, the EEG was improved in two-thirds of patients including those with CSWS syndrome. No significant changes were seen in the serum concentrations of anti-epileptic drugs during the remission. Possible reasons for the resolution of seizures in these patients are: (1) an immunologic or inflammatory processes; (2) increased serum concentration levels of anti-convulsant due to dehydration with the illness; (3) increased levels of antibodies after viral infections (similar to immunoglobulin therapy in intractable epilepsies; (4) suppression of immunopathological processes by anti-inflammatory cytokines, such as interleukin-10 and transforming growth factor- β .

Table 1
The classification of epilepsy or epileptic syndromes encountered (*n*)

West syndrome and subsequent epilepsy post West syndrome (16)
Cryptogenic type (3), symptomatic type (13)
Lennox-Gastaut syndrome (2)
Symptomatic localization-related epilepsy (1)
Severe myoclonic epilepsy in infancy (1)
Continuous spike-waves of slow sleep (1)

Table 2
The types of infectious diseases encountered (*n*)

Probable common cold (5)
Rotavirus gastroenteritis (4)
Exanthema subitum (4)
Upper respiratory infection (3)
Measels (3)
Mumps (1)
Cytomegalovirus infection (1)

4. Discussion

Patients with intractable epilepsy in infancy, particularly West syndrome, rarely show spontaneous remission of seizures. This aspect of the natural history of these epilepsies has been insufficiently recognized. Hrachovy reported that spontaneous remission of West syndrome may occur as early as 1 month after spasm onset and the remission rate increased to 25% 12 months after onset without effective therapy, such as adrenocorticotropic hormone (ACTH) or valproate, but author did not describe any events triggering spontaneous remission [1]. The disappearance of seizures most often occurs following a viral infection. West first described in his syndrome a patient with such a remission after a brief febrile illness [2]. Some patients with intractable epilepsy respond to the therapy with immunoregulatory or anti-inflammatory agents such as high-dose immunoglobulin, ACTH or corticosteroids [3, 4]. The participants of the present survey proposed the following mechanisms for the disappearance of intractable epileptic seizures following acute viral infections: increased serum concentrations of anti-epileptic drugs with secondary to dehydration, increased levels of antibodies after viral infections (similar to immunoglobulin therapy), and the suppression of immunopathological processes by anti-inflammatory cytokines, such as interleukin-10 or transforming growth factor- β . Increased vascular permeability of blood–brain barrier under the condition in the intractable epilepsies, such as West syndrome or Lennox-Gastaut syndrome was proposed by Ariizumi et al. [5]. The increased vascular permeability allows immunoglobulins to easily cross the blood–brain barrier following acute viral infections (also similar to immunoglobulin therapy). However, these speculations are not based on the experimental or laboratory data. In this study, we could not find a reasonable explanation as to the relationship between the spontaneous improvement of intractable epilepsies and acute viral infections. In 2002, Hattori identified the spontaneous remission of spasms following acute viral infections in 25 patients with West syndrome on the base of data analysis of Japanese medical literature between 1970 and 2000 [6]. In this study, exanthema subitum was most predominant infectious disease that

leads to resolution of the seizures. He also stated that these spontaneous remissions following acute viral infections have not been duly appreciated in the English medical literature. Better understanding of such mechanisms may lead to a new therapeutic approach to intractable epilepsies in infancy.

The participants in the survey:

- Kimio Minagawa (Otaru)
- Eiji Nakagawa (Tochigi)
- Masatoshi Ito (Shiga)
- Tomiyuki Akiyama (Okayama)
- Harumi Yoshinaga (Okayama)
- Shigeru Yanagaki (Tokyo)
- Mana Kurihara (Atsugi)
- Toshio Hanai (Fukuoka)
- Tomoyuki Nakazawa (Tokyo)
- Toshiyuki Iwasaki (Sagamihara)
- Hitoshi Ueda (Osaka)
- Hiroshi Murakami (Kawasaki)

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We would like to thank those who participated in the survey.

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**SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK**

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

v.

Dept. of Health & Mental Hygiene of the City of New
York,

Defendant-Respondent.

No. _____

**MEMORANDUM OF LAW IN SUPPORT OF VERIFIED
ARTICLE 78 PETITION AND DECLARATORY JUDGMENT PETITION**

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Plaintiffs-Petitioners respectfully submit this Memorandum of Law in support of Plaintiffs-Petitioners' Verified Article 78 and Declaratory Judgment ("Petition"), filed concurrently herewith.

PRELIMINARY STATEMENT

In the spring of 2019, New York City experienced a rise in measles cases. Measles is a childhood infection caused by a virus that, before the 1960s, nearly all children contracted before the age of 15. Most measles cases are benign and are not reported. (**Ex. A**).¹ The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in the United States. (**Exs. A and B**). In 1962, a year before the first measles vaccine, when there were approximately 4 million cases of measles each year, the Centers for Disease Control ("**CDC**") reported a total of 408 deaths from measles in the entire United States.

Between September 2018 and August 2019, 649 cases of measles were confirmed in New York City. Since 2000, the annual number of reported measles cases for all of the United States ranged from 37 people in 2004 to 667 people in 2014. While 600 cases in New York City alone was, relatively speaking, an unexpected increase in cases, it was a very small number in a city of over 8,000,000. While over 1,200 cases of measles were reported in the tri-state area and likely far more unreported cases, there were no deaths. This is the expected result since, for the majority of people, measles is a relatively benign childhood infection.

Despite the small outbreak, the New York City Department of Health ("**DOH**") overreacted to the 2019 increase in measles cases. On Friday, April 9, 2019, Oxiris Barbot, the then New York City Commissioner of Health and Mental Hygiene (the "**Commissioner**") issued

¹ All Exhibits referenced in this Memorandum of Law, and in the jointly filed Verified Article 78 and Declaratory Judgment Petition and Affirmation of Elizabeth A. Brehm, are exhibits admitted without objection at the OATH hearing, described further herein, or are otherwise part of the administrative record.

an Order mandating that people receive the M-M-R-II, also known as the measles, mumps, rubella vaccine (“**MMR**”) manufactured and sold by Merck & Co., within forty-eight hours (the “**Commissioner’s Order**”). (Ex. C). The Commissioner’s Order though, was limited to only selected people in certain zip codes and was not evenly applied across the city. Specifically, the Order required MMR vaccination only of certain people: any person “older than six months of age who live[d], work[ed], or reside[d] within the 11205, 11206, 11211 and/or 11249 zip codes.” *Id.*

By its terms, the Commissioner’s Order expired on April 17, 2019. (Ex. D at 56:23-57:7; 63:23-64:2). On that day, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “**Board**”) created a resolution which, like the Commissioner’s Order, required administration of the MMR, but differed from the Commissioner’s Order in myriad ways. These differences included: how it defined what the “nuisance” was that it was targeting, what categories of individuals it applied to, the age ranges to which it applied, the penalties for failure to vaccinate, and other material differences as detailed below (the “**Resolution**”). (Ex. E).

Between April 23, 2019, and June 14, 2019, the New York City Department of Health and Mental Hygiene (“**DOH**”) issued a Summons to each of the Plaintiffs-Petitioners, asserting that each had failed to have one of their minor children injected with the MMR (the “**Summonses**”). The Summonses clearly and prominently alleged that this failure to vaccinate violated the Commissioner’s Order, not the Resolution. However, the DOH issued each of the Summonses after the Commissioner’s Order expired, making each Summons facially invalid. (Ex. F).

Plaintiffs-Petitioners had a reasonable and well-founded belief that they should not administer the MMR to their children (the “**children**”) for many reasons, including, *inter alia*:

The clinical trials conducted on the MMR were severely lacking in adequate safety studies because (i) the studies did not test the product against a placebo, (ii) the studies did not test the

product on a large enough group of children of an appropriate age range, (iii) the studies did not review safety for an adequate time period, and, (iv) during the minimal safety review period, the safety studies showed concerning adverse events;

Medical studies have shown that depriving children of having naturally occurring measles increases their risks of other adverse health outcomes; and

The medical community has documented high rates of hospitalization and emergency room visits subsequent to MMR administration.

Based on these concerns, Plaintiffs-Petitioners made the decision that the risks of the product outweigh the benefit, and that administering MMR to their children is not medically appropriate.

Given the facial defects in the Summonses and their well-founded concerns about the MMR product, Plaintiffs-Petitioners fought the Summonses in OATH where, despite making compelling arguments and presenting un rebutted evidence supporting the above issues, the hearing officer upheld the Summonses, and the OATH Appeals Unit affirmed those decisions on April 24, 2020. (**Ex. G**).

The hearing record, however, reflects that the Summonses should have been dismissed and that the Hearing Officer deprived Plaintiffs-Petitioners of full and fair hearings, made errors of law, and issued arbitrary and capricious decisions. (*Infra* § First Cause of Action.)

The OATH Appeals Unit should also have dismissed the Summonses in the interest of justice pursuant to NYCC § 1049(5)(a) because the undisputed evidence at the hearing demonstrated that the risk of administering the MMR to these children outweighed the benefits and therefore it was not medically appropriate to inject them with this product. (*Infra* § Second Cause of Action).

By requiring the injection of a product whose risks outweigh the benefits for these children, Respondent's Order and Resolution also violated Plaintiffs-Petitioners' rights under the United States Constitution and New York State Constitution, including the right to bodily integrity, informed consent, parental choice, privacy, and other substantive due process and unenumerated rights. (*Infra* § Third Cause of Action.)

Plaintiffs-Petitioners thus bring this hybrid petition pursuant to CPLR §§ 7801-7806 to set aside and vacate the Summonses.

ARGUMENT

The Summonses issued by the DOH should be set aside and vacated, *inter alia*, as unjust and violative of the United States Constitution and the New York State Constitution.

I. THE DEFENDANT-RESPONDENT ACTED ARBITRARILY, CAPRICIOUSLY, AND CONTRARY TO LAW BY UPHOLDING THE SUMMONSES

It is black letter law that a summons must identify the exact law, regulation, or order that the charging officer claims the recipient violated. RCNY § 6-08(c)(2) and (c)(3). It is equally well established that such a law, regulation, or order must be in effect at the time of the alleged violation. Here, the Summonses failed on both accounts.

The DOH issued the Summonses between April 23, 2019 and June 14, 2019. The charging language of the Summonses provides that Plaintiffs-Petitioners were in violation of the Commissioner's Order. However, the Commissioner's Order by its terms expired on April 17, 2019. Given this defect, the OATH Appeals Unit reasoned that the Summonses were actually issued under the Board's Resolution, but that is not what the Summonses say, and the Resolution is significantly different from the Order in a number of ways. Thus, the Summons either cite an order that had expired, or they cited to the wrong order. Either way, the Summonses are facially deficient and should have been dismissed.

The narrative portions of the Summonses specifically reference both the Commissioner's April 9, 2019 Order, which they define as the "Order", and the Board's April 17, 2019 resolution, defining it as the "Resolution." (Ex. F).² Nevertheless, the charging language of the Summonses identifies the violation as being a violation of the *Order*, providing in full that: "Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*." *Id.* (emphasis added.) As such, the summonses are clear that they allege a violation of the Order, and not of the Resolution. (Ex. F).

During the hearings on the Summonses, the DOH conceded that the Commissioner's Order expired on April 17, 2019. (Ex. D at 56:34-57:7; 63:23-64:2). The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" Health Code of the City of New York, 24 RCNY § 3.01(d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

² The full text of the "Violation Description" provides as follows and clearly defines both the Resolution and the Commissioner's Order, recognizing them as separate, but then choose to only state that the Plaintiffs-Petitioners are in violation of the Order: "In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, [initials], who is at least six months old, lives at: [address] which is located in one of the affected zip codes listed in the Order. On [date], a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child [initials] has no record of measles immunization. Respondent has failed to vaccinate child [initials] or otherwise submit proof of immunity *in violation of the Order*." (Ex. F) (emphasis added).

The Summonses each listed a “Date and Time of Occurrence” after April 17, 2019.³ (**Ex. F**). Therefore, the Order had expired by the time the Summonses were issued, and it was an error of law for the Hearing Officer and Appeals Unit to affirm the Summonses because the Commissioner’s Order had expired by the date of the occurrence listed on the Summonses. (**Exs. C and F**). On this basis, the Summonses must be dismissed.

During the hearing, the DOH argued that despite the fact that the Order expired before the Summonses were issued, the Resolution continued the Commissioner’s Order, and thus the Commissioner’s Order was still valid on the date of occurrence on the Summons. This argument is plainly incorrect. The New York City Health Code provides that “the Board may *continue* or *rescind*” the Order. Health Code of the City of New York, 24 RCNY § 3.01(d) (emphasis added). On its face, that section allows the Board only to continue the order “as is” or to rescind the order and issue a new order. Nothing in that section states that the Board may *amend* the emergency order.

In this instance, the Board did not continue the Commissioner’s Order. Even though the Resolution acknowledges the Commissioner’s Order in the preamble, nothing in the Resolution states it is continuing the Commissioner’s Order. Instead, the Board allowed the Commissioner’s Order to expire and subsequently issued the Resolution, which was a new order, with materially different terms. Even a cursory examination of a few of these terms establishes that the Commissioner’s Order and the Resolution, although they address the same topic, are two different directives, and as such, one is not a continuation of the other.

³ Plaintiffs-Petitioners’ Summonses listed the following “Date and Time of Occurrence:” Berkowitz Summons: June 4, 2019; Biederman Summons: April 29, 2019; Englander Summons: May 1, 2019; Fishman Summons: June 12, 2019; Fried Summons: May 10, 2019; Friedman Summons: June 4, 2019; Fulop Summons: May 22, 2019; Guttman Summons: June 13, 2019; Josef Summons: June 4, 2019; Klein Summons: May 1, 2019; Roth-Tabak Summons: April 21, 2019. (**Ex. F**).

First, the Resolution redefines what constitutes a nuisance. The Order defines the nuisance as the presence of a person who was not vaccinated with MMR.⁴ The Resolution defines the nuisance as the measles outbreak.⁵

Second, the Resolution materially changed who must receive an MMR vaccination, as well as the grounds and method for being excluded from this requirement:

The Commissioner's Order does not include children who attend school, preschool, or child care in the affected zip codes (it only includes "any child older than six months of age who *live[], work[] or reside[] within the*" affected zip codes), whereas the Resolution explicitly includes children who "attend[] school, preschool or child care within the affected zip codes." (**Ex. C**).

The Commissioner's Order applies to children "older than six months," but the Resolution applies to children "six months of age and older." (**Exs. C and E**). Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas under the Resolution, six-month-old babies were required to be vaccinated.

The Commissioner's Order includes people who "live, work, or reside[]" in the affected zip codes, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. (**Exs. C and E**). The Board's decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile."⁶ Conversely, that same dictionary defines

⁴ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" (**Ex. C**).

⁵ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" (**Ex. E**).

⁶ Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>.

“live” as: “to pass through or spend the duration of[.]”⁷ Thus, the Commissioner’s Order, by use of the term “reside,” includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (*e.g.*, people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution is limited to the people who are physically present in the area.

The Commissioner’s Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of the DOH.⁸

Third, the penalties for the Commissioner’s Order are different than the penalties for the Resolution. The Commissioner’s Order includes a “warning” that “[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.” (Ex. C). The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code, 24 RCNY § 3.11 (a), and subjecting violators to fines for each family member and for each day a person violates the Resolution. This “enhanced” civil penalty did not appear in the Commissioner’s Order but is included in the “resolved” language of the Resolution.⁹

⁷ Merriam-Webster’s Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>.

⁸ The terminology may seem similar between the Commissioner’s Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

⁹ “RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.” (Ex. E).

In sum, the Resolution materially changed the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, which means that per the requirements of the Health Code of the City of New York, 24 RCNY § 3.01(d), the Commissioner's Order expired on April 17, 2019.¹⁰ Thus, the Board's assertion that the Plaintiffs-Petitioners violated the Order was *per se* unlawful.

Despite the clear differences between the Order and the Resolution, the Hearing Officer still held in his written decision that the "April 17, 2019 Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order." (**Ex. G**). As shown, this finding is not supported by the facts and law. The Hearing Officer could not even quote any language from the Resolution stating it continues the Order, because such language does not exist; that is why he resorted to stating that the "Resolution continued the Commissioner's exercise of emergency authority." As noted, that is not what the law provides. The Order as it was written must either be continued or rescinded; the Board cannot choose to continue the Order in concept while changing most of its terms.

This case provides a ready example of why the Board was not allowed to amend an existing order, because otherwise a summons recipient could be told he or she violated one order, choose to mount a defense to that order, but only later learn that they actually are being charged with

¹⁰ The Summons issued to one of the Plaintiffs-Petitioners was not properly served. The Summons issued to Plaintiff-Petitioner Chava Biederman ("**Ms. Biederman**") should be dismissed because Ms. Biederman does not reside at the address listed on the Summons as the "Place of Occurrence" and Ms. Biederman was not present at the "Place of Occurrence" when the alleged violation took place on April 29, 2019. Ms. Biederman presented sufficient and reliable evidence at the hearing that she did not live or reside at the "Place of Occurrence" as listed on the Summons and was not present at that location on the time and date of occurrence. (**Ex. H**). Therefore, it was an error of law for the Hearing Officer and Appeals Unit to sustain the Summons because no violation existed as alleged, and thus the Summons issued to Ms. Biederman must be dismissed.

violating and being punished under a materially different order. This presents a problem here because the Order and the Resolution provided conflicting provisions as to, *inter alia*, the individuals who were required to receive MMR, the penalties for not receiving the MMR, and the method and grounds for obtaining a medical exemption. As a matter of both fact and common sense, they both cannot exist in the same time and space. This bait-and-switch version of justice, where a litigant does not have proper notice of what they are accused of, flies in the face of the basic presumptions of due process.

Tellingly, the OATH Appellate Unit did not affirm the OATH Hearing Officer's flawed conclusion that the Resolution continued the Order. The OATH Appellate Unit apparently found it to be without merit. Instead, the OATH Appellate Unit decided that since the children presumably did not have the MMR during the period the Order *was* in effect (giving no consideration to the period after the Order expired), then it would uphold the Summonses by effectively rewriting them; instead of the "Date and Time of Occurrence" for the violation listed on the Summonses, the OATH Appellate Unit decided it would simply find the Plaintiffs-Petitioners in violation for a completely different time period: the 48 hours specified in the Order.

The problem with the OATH Appellate Unit's decision is that it apparently changed the Summonses that were being adjudicated *ex post facto* - after the hearing record was closed -which it cannot do.

It is elementary and critical to due process that a respondent only be judged on and punished for what the summons charges. Here, that charge was for violation of the Order on a date after it expired, not for a violation that occurred on some other date first raised in a decision by an appellate body. That is the antithesis of due process and the orderly manner in which justice is supposed to proceed.

II. NYCC § 1049(5)(A) CALLS FOR THE DISMISSAL OF THE SUMMONSES IN THE INTEREST OF JUSTICE

Section 1049(5)(a) of the NYCC provides:

*An administrative law judge or hearing officer may dismiss a notice of violation in the interest of justice when, even though there may be no basis for dismissal as a matter of law, such dismissal is appropriate as a matter of discretion due to the existence of one or more compelling factors, considerations, or circumstances clearly demonstrating that finding the respondent in violation of the provision at issue would constitute or result in injustice.*¹¹

The Summonses should have been dismissed pursuant to NYCC § 1049(5)(a) because the undisputed evidence entered at the hearing reflected that the risk of injecting the MMR into these children outweighs any benefits. Plaintiffs-Petitioners presented significant evidence establishing this as a fact, and the DOH never once objected to or refuted any of that evidence. Therefore, for purposes of this matter, it is an established fact that MMR presents greater dangers than the benefits it brings. If the interest of justice does not tip in favor of dismissal when the evidence incontrovertibly reflects the injustice of a risk of increased harm to a child, then the safeguard afforded by NYCC § 1049(5)(a) is meaningless.

The first vaccine for measles was licensed in the United States in 1963. (Ex. A). According to the CDC, the mortality rate from measles declined by over 98% between 1900 and 1962. (Exs. A and B). In 1962, the CDC reported a total of 408 deaths from measles in the United States. (Ex. D at 207:18-21). The CDC reported a similar total number of measles deaths in the United States for a number of years prior to 1962. (Ex. B). What this means is that prior to 1962, at a time when virtually every American had the measles, the CDC's data makes clear that the annual death rate from measles was 1 in 500,000 Americans.

¹¹[http://library.amlegal.com/nxt/gateway.dll/New%20York/charter/newyorkcitycharter?f=templates\\$fn=default.htm\\$3.0\\$vid=amlegal:newyork_ny](http://library.amlegal.com/nxt/gateway.dll/New%20York/charter/newyorkcitycharter?f=templates$fn=default.htm$3.0$vid=amlegal:newyork_ny) (last visited August 17, 2020) (emphasis added).

There would likely be even fewer deaths from measles today, since medical care has made significant advances since 1962. But even assuming the same medical care today as in 1962, the unrebutted science admitted at the hearing makes clear that the measles vaccine MMR causes more deaths every year than the 400 individuals lives it theoretically saves annually.

Indeed, eliminating measles has demonstrably and measurably increased certain cancer rates as well as the risk of heart disease.¹² The International Agency for Research on Cancer has confirmed that those who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma and a 233% increased rate of Hodgkin Lymphoma. (**Exs. L-P**). These two cancers killed 20,960 Americans in 2018. *Id.* Plaintiffs-Petitioners presented copious evidence supporting this conclusion at the hearing without objection and the DOH never attempted to rebut that evidence.

Likewise, researchers at the Department of Health Care and Epidemiology at the University of British Columbia and the Department of Biology at the University of Victoria have confirmed that those who never had measles had a 50% increased rate of ovarian cancer, which killed 14,070 Americans in 2018. (**Exs. Q-R**). Again, this was accepted at the hearing without objection and remained unrebutted.

Even more troubling was the fact that the nation of Japan concluded, after tracking over 100,000 of its citizens for more than 22 years, that having measles and mumps was “associated with lower risks of mortality from heart disease,” which killed 610,000 Americans in 2018. (**Exs. S-T**). Once again, Plaintiffs-Petitioners presented the evidence establishing this fact on the record without objection, and Defendant-Respondent never once presented anything to rebut that evidence.

¹² Additionally, **Exs. I-K** reflect that children who have had measles have far less allergies and atopic diseases, such as asthma, and adults who had measles have a reduced risk of Parkinson’s Disease. It is not medically appropriate or just to increase an individual’s risk of allergies, atopic diseases, or Parkinson’s Disease.

Until the introduction of the vaccine, measles was considered a mild childhood infection, like the chickenpox used to be. The ecological relationship humans developed with measles over millennia did not eliminate measles or ensure that only those that survived were those that were immune to the disease because it conferred benefits for survival that exceeded its negative effects.

Hence, the unrebutted evidence shows that eliminating measles has likely caused far more deaths annually in the United States from cancer and heart disease than the potentially few hundred lives saved from the elimination of measles.

The foregoing facts presented at the hearing demand that the Summonses be dismissed because the accepted and unrebutted evidence demonstrates an increased, not decreased, risk of mortality from complying with the Order. The DOH was given every opportunity to rebut this evidence yet chose not to do so.¹³

¹³ The DOH and Dr. Rosen objected to none of the admitted evidence at the hearing nor did they rebut any evidence. They had myriad opportunities to oppose, contest, or dispute this evidence being entered into the record and they did not:

MR. LEUNG: Well, let me just say something. These are both hearings and attorney statements. When you come in, it is testimony to the extent that your introducing these documents. And you can testify in place of your client.

MR. SIRI: Okay.

MR. LEUNG: You can testify in place of the client's doctor. You can testify -- triple hearsay is permitted. Whatever you need to say, I'm taking into consideration. Everything is testimony

...

MR. LEUNG: The documents that have been admitted so far all the way up to Respondent's 39. Department of Health, any objections? Any objections to those being admitted into evidence?

MR. MERRILL: No objections.

MR. LEUNG: Okay. They're admitted into evidence.

...

MR. LEUNG: But you spoke at length and I want to give the Department of Health, Mr. Merrill, an opportunity to address all the issues that they have. Is there anything else that you want to add?

MR. MERRILL: No.

...

MR. LEUNG: ... I have given a chance to the Department of Health to review that. Any objection going up to R-45?

MR. MERRILL: No, your Honor.

MR. LEUNG: Hearing no objections, these are admitted into evidence. And hearing nothing further from either parties; is that correct.

MR. MERRILL: That's right.

The DOH brought Dr. Jennifer Rosen to the OATH hearings to testify as the agency's physician.¹⁴ Dr. Rosen's resume shows that she had significant training and experience in childhood immunization, including through her work at the Howard Hughes Medical Institute and the CDC. Since 2009, Dr. Rosen has been at the New York City Department of Health and is currently the Director of Epidemiology and Surveillance for the Bureau of Immunizations. There, she oversees surveillance and outbreak investigations for vaccines and preventable diseases, including measles.

Not only did the DOH and Dr. Rosen not object to, nor provide any evidence to contradict, what Plaintiffs-Petitioners presented during the first hearing date, August 28, 2019, but they also did not do so when they had a second bite at the apple during the follow-up hearing date, September 25, 2019.

The fact that this evidence went un rebutted means that, based on the record presented during the hearing, Plaintiffs-Petitioners established that the Order requires Plaintiffs-Petitioners to inject a product into their children that has been medically established to increase mortality, and will expose their children to far greater risks of a number of conditions later in their lives.

(Ex. D at 211:7-20; 226:24-227:11; 239:2-9; 242:9-243:7).

¹⁴ Because of the proven potential for adverse events following this product, and because the Summons calls for a fine to Plaintiffs-Petitioners "unless they demonstrate...that immunization is not medically appropriate," counsel for Plaintiffs-Petitioners proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. "A respondent may request the [issuing officer's] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful." *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). The Defendant-Respondent objected and argued the issuing officer was not necessary since Dr. Rosen was available and could answer any questions. (Ex. D at 9:1-9:20). Based on same, the Hearing Officer declined Plaintiffs-Petitioners' application to cross-examine the issuing officer, holding that Dr. Rosen was available and could answer any questions regarding these disputed facts. (Ex. D at 14:4-22).

In addition, the following facts regarding the harms from this product also remained un rebutted.¹⁵

The Order requires injection of M-M-R-II,¹⁶ a product which was licensed by the FDA based on clinical trials which had a total of 834 children, had no placebo control, and only reviewed safety for 42 days after injection. (**Ex. BB**). Putting aside the lack of placebo control, even if the clinical trials were properly controlled, they did not have enough individuals to assess safety; nor did they review safety for long enough. They also included children of limited ages: most were ages 11 months to 8 years old, while the Order is seeking to have M-M-R-II used by children aged 6 months.¹⁷

Despite the fact that approximately a third of the children in the clinical trials developed gastrointestinal issues and respiratory issues within 42 days of receiving the MMR, due to their underpowered size and lack of follow-up, they were able to avoid this being a roadblock to licensure. Despite MMR being licensed, the clinical trials clearly did not, as they could not, confirm that the product was safe, and certainly not for any period longer than 42 days, nor for even the 42 days they did review safety. For example, the below table is the safety data from one

¹⁵ Physicians have separately detailed the benefits and risks of the MMR in **Ex. A**.

¹⁶ **Ex. V** lists the excipient and media contained in the MMR, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin. **Exs. W-Y** are product descriptions and history of the use of these ingredients and excipients. **Ex. Z-AA** explain the existence of aborted fetal cells' use in vaccines and the potential adverse effects of such use.

¹⁷ It was, therefore, arbitrary and capricious for the Hearing Officer to sustain the Summonses mandating the MMR for a child less than twelve months old. Plaintiff-Petitioner Judith Fried's ("**Ms. Fried**") child was 9 months old at the time of the alleged violation. (**Ex. CC**). However, the Food and Drug Administration ("**FDA**") has not licensed MMR for children less than twelve months old. Ms. Fried presented undisputed evidence at the hearing that the MMR is not licensed for this age group and that the "safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established." (**Ex. DD**). Therefore, the Summons and the Hearing Officer's order are both saying that Ms. Fried's child must receive the MMR even though the FDA has not determined that it is safe or effective for the child. This is patently arbitrary and capricious because there is no reasonable basis for the Hearing Officer to uphold a violation for failure to inject a child with MMR where the vaccine is not licensed for use in the child. Finally, the Hearing Officer failed to address this argument in his written decision, further making the decision arbitrary and capricious.

of the largest clinical trials, which had a total of just 102 children injected with MMR, relied upon to license MMR:

Table 10

Clinical Complaints Reported Among Children Who Received a 0.5 ml Dose of Combined Live Measles-Mumps-Rubella (MMR) Virus Vaccine, Lot No. 621/C-0763 (Study 1463)

Clinical Complaint	Total Vaccines (102 Children)					No. with Complaint	Initially Seronegative for Measles, Mumps and Rubella (58 Children)					No. with Complaint
	Days Post-Vaccination						Days Post-Vaccination					
	0-4	5-12	13-18	19-28	29-62		0-4	5-12	13-18	19-28	29-62	
Soreness at Injection Site	4 (4.2%)			1 (1.0)		5	2 (3.0)					2
Lymphadenopathy	2 (2.1)	3 (3.1)		3 (3.1)	2 (2.1)	8	1 (1.3)	1 (1.5)		3 (3.0)	2 (3.0)	3
Measles-like Rash	1 (1.0)	9 (9.4)	6 (6.2)	1 (1.0)		11	1 (1.3)	7 (10.4)	5 (7.5)	1 (1.5)		8
Arthralgia			1 (1.0)	1 (1.0)		2			1 (1.5)	1 (1.5)		2
Myalgia		1 (1.0)				1		1 (1.5)				1
Irritability	3 (3.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	4	2 (2.8)	2 (2.9)	1 (1.5)	1 (1.5)		5
Headache	2 (2.1)	2 (2.1)				2	2 (3.0)	2 (3.0)				2
Upper Respiratory Illness	18 (31.6)	37 (36.5)	24 (25.4)	35 (36.5)	32 (33.3)	64	28 (41.8)	27 (40.3)	20 (29.8)	25 (37.3)	28 (42.8)	48
Diarrhea	1 (1.0)	7 (7.3)	2 (2.1)	5 (5.2)	4 (4.2)	14	1 (1.5)	4 (6.0)	2 (3.0)	3 (4.5)	2 (3.0)	9
Ophthalmopathy	2 (2.1)	3 (3.1)	2 (2.1)	4 (4.2)	7 (7.1)	6	2 (2.8)	3 (4.5)	2 (3.0)	4 (6.0)	3 (4.5)	6
Gastrointestinal Illness	18 (31.6)	28 (29.0)	8 (9.4)	17 (17.2)	15 (15.4)	43	18 (26.9)	19 (28.4)	9 (13.4)	14 (20.9)	11 (16.5)	33
Anorexia	13 (13.5)	19 (19.8)	8 (8.3)	10 (10.4)	13 (13.5)	28	10 (14.9)	12 (17.9)	6 (9.0)	9 (13.4)	11 (16.4)	20
Fatigue				1 (1.0)		1				1 (1.5)		1
Fish-Chafing, Diaper, Heat, Herpes	4 (4.2)	6 (6.2)	1 (1.0)	4 (4.2)	5 (5.2)	12	3 (4.5)	4 (6.0)	1 (1.5)	1 (1.5)	3 (4.5)	9
Allergy, Asthma	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)	2 (2.1)	8		1 (1.5)	2 (3.0)	1 (1.5)		3
Fever	1 (1.0)	1 (1.0)		2 (2.1)	1 (1.0)	4		1 (1.5)		1 (1.5)		2
Sudorexia	1 (1.0)					1	1 (1.5)					1
Teething	3 (3.0)			1 (1.0)	3 (3.0)	4	1 (1.5)			1 (1.5)	2 (3.0)	4
Persons with Complaints:	50 (52.1)	50 (52.1)	31 (34.4)	43 (44.8)	42 (45.8)	78	36 (55.7)	38 (56.7)	28 (41.5)	32 (47.8)	34 (51.8)	58
Persons with No Complaints:	42 (47.9)	44 (47.9)	63 (65.6)	53 (55.2)	52 (54.2)	55	29 (43.3)	29 (43.3)	38 (56.7)	35 (52.2)	37 (55.2)	58
Negative Physician Surveillance	6	6	6	6	6	6	1	1	1	1	1	1

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The table above shows that of 102 children injected with MMR, 64 of them, or nearly 63%, experienced gastrointestinal illness and that 43, or 42%, of the children experienced upper respiratory illness within the first 42 days following administration. All of the foregoing was accepted without objection during the hearing.

The following un rebutted facts confirm that there are also numerous safety issues with this product that have arisen after licensure.¹⁸

¹⁸ Exs. EE-II are reports from the IOM which looked at the components of the MMR. The IOM looked at the 22

Federal law expressly provides that the package insert for a vaccine like M-M-R-II should include “*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.” *See* 21 C.F.R. 201.57 (**Ex. D at 217:19-218:16**). The package insert for M-M-R-II lists approximately 60 such adverse reactions that Merck has identified, many of which are serious and debilitating. (**Ex. DD**). For instance, during the hearing, Plaintiffs-Petitioners introduced into evidence two examples of Merck recently adding adverse reactions to its M-M-R-II package insert. The first was the addition of “transverse myelitis” (neurological dysfunction of the spinal cord) which was added to the list in 2014; and “Henoch-Schonlein purpura” (a vascular disease that primarily affects small blood vessels) and “acute hemorrhagic edema of infancy” (a type of leukocytoclastic vasculitis which manifests with fever, large palpable purpuric skin lesions, and edema) which were added to the list in 2017. (**Ex. JJ**).

The CDC even discloses that MMR can cause deafness, long term seizure, coma, and brain damage.¹⁹ (**Ex. KK**). An example of such an injury involving a \$100 million award to the victim of an MMR injury was presented at the hearing. (**Ex. LL**). The CDC and FDA also jointly operate the Vaccine Adverse Events Reporting System (“VAERS”) which, as an example provided at the OATH hearing, reflected 1,256 hospitalizations and/or emergency room visits in one year following MMR vaccination. A report from Harvard researchers, under a federal grant, stated that VAERS reflects fewer than 1% of vaccine adverse events.

most commonly claimed serious adverse reactions after the MMR and reported that, for 18 of the 22, they were *not able to determine* whether or not the MMR components caused them due to a lack of science. The IOM stated: “The lack of adequate data regarding many of the adverse events under study was a major concern to the committee.” The IOM further explained that “most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility” yet no studies have been conducted to identify those who are susceptible.

¹⁹ And like most vaccines, the MMR has never been evaluated for its potential to cause cancer, to mutate genes, or to cause infertility. (**Ex. DD**).

This high rate of hospitalization and emergency room visits from MMR is likewise confirmed in a study conducted by Canadian health authorities of 271,495 children after their 12-month MMR. The Canadian health authorities set out to confirm the safety of MMR, but what they found instead was that “[t]here was a significantly elevated risk of primary emergency room visits approximately one to two weeks following 12- and 18-month vaccination.” (Ex. MM). This amounted to an additional “one event for every 158 vaccinated” children receiving MMR. Extrapolating these figures to the United States, it means that 63,291 additional children would be going to the hospital each year from MMR after their MMR vaccine (based on the CDC’s representation that, each year in the United States, nearly 10 million doses of MMR are distributed).

Dr. Rosen also did not refute or even dispute any of the evidence regarding post-marketing safety issues with MMR at the hearing; in fact, all this evidence was accepted without objection.²⁰

After the current MMR’s licensure in 1978, its use in children steadily increased and lawsuits from injuries from this product also began to snowball. Indeed, by the mid-1980s – when the only two commonly injected childhood vaccines were MMR and DTP – pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products. (Ex. D at 184:24-186:18, Ex. NN). As the United States Supreme Court explained in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011): “by the mid-1980’s ... the remaining [vaccine] manufacturer estimated that its potential tort liability exceeded its annual sales by a factor of 200.”²¹

²⁰ See paragraphs 42-45, supra. Additionally, Dr. Rosen was not able to rebut that the risks outweigh the benefits for these children even though most of the hearing time was devoted to the Hearing Officer improperly interjecting to protect Dr. Rosen from difficult questions and/or Dr. Rosen refusing to provide responsive answers to questions. (Ex. D at 153:14-18 and generally).

²¹ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011).

Instead of letting the usual market forces drive pharmaceutical companies to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), in 1986, which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccine products.²²

While the manufacturers of the MMR and other childhood vaccines have paid billions of dollars for misconduct and injuries related to their drug products, these same companies cannot be held accountable for misconduct and injuries resulting from their vaccine products, including the MMR. (**Ex. OO**). Dr. Jennifer Rosen, the DOH’s physician who testified at the OATH hearing and who the DOH said could answer any questions Plaintiffs-Petitioners had, was not aware of this fact.²³

When provided an opportunity to rebut any of the foregoing evidence, the DOH declined to proffer any evidence in rebuttal, accepted the foregoing evidence without objection, and despite prodding from the Hearing Officer, neither the DOH nor Dr. Rosen had any additional argument, statement or evidence to present to rebut any of the foregoing.

Indeed, when provided multiple opportunities to object to any of this evidence, the DOH declined to do so. The Hearing Officer repeatedly asked for objections: “Department of Health, any objections? Any objections to those being admitted into evidence?” DOH’s attorney repeatedly responded: “No objections.” (**Ex. D at 227:6-11**). After additional evidence was

²² 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

²³ “Q. So you are not aware that the manufacturer of the MMR vaccine, Merck, cannot be sued for injuries caused by their MMR vaccine? A. I am not familiar with the process for manufacturing companies. Q. Are you aware -- but are you aware that -- if you could answer yes or no on that one. A. No, I am not aware. Q. You are not aware of that. So you are not aware that Merck can[not] be sued for injuries caused by the MMR vaccine? A. No.” (**Ex. D at 101:24-102:12**).

entered, the Hearing Officer again gave the DOH the chance to object: “Any objection going up to R-45?” DOH’s attorney responded, “No, your Honor.” (**Ex. D at 242:9-17**).

Thus, the undisputed evidence reflects that the mandated MMR was not medically appropriate for the children, as the risks of injecting this product into the children outweigh the benefits.²⁴

For these reasons, the record here reflects that the DOH is seeking to mandate injection of a liability-free product that has not been proven to be safe and whose risks outweigh any believed benefit. The potential adverse events that can follow the administration of the MMR and the lack of support for their benefit overshadow any rash overreaction by the DOH. Imposing a fine on these families for choosing what the evidence reflects is best for their children’s overall health is unjust. The Court should, therefore, find that Respondent’s final determinations are affected by an error of law and are arbitrary and capricious.²⁵

III. REQUIRING INJECTION OF M-M-R-II VIOLATES THE UNITED STATES AND THE NEW YORK CONSTITUTIONS

The Commissioner’s Order and Resolution violate the New York and United States Constitutions.

Because the un rebutted record reflects that the risk of injecting a medical product outweigh its benefits, including a significant increased risk of mortality from being injected with the product, the United States Constitution and New York State Constitution extend their shield of protection to prevent the government from requiring such an injection.

²⁴ Indeed, the one study that looked at health outcomes of children who were vaccinated versus children who were not vaccinated found that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders than the unvaccinated. *See Ex. PP*. It is not medically appropriate or just to force an individual to trade avoidance of a limited infection for a chronic health condition.

²⁵ Plaintiffs-Petitioners admitted additional, un rebutted evidence at the OATH hearings. Those exhibits are appended at **Exs. QQ-XX**.

Specifically, requiring injection of M-M-R-II into the bodies of the Plaintiffs-Petitioners' children violates both federal and state constitutional rights to substantive due process, bodily integrity, informed consent, parental choice, privacy, unlawful search and seizure, other unenumerated rights, and the First Amendment protection of freedom of religion.

A. Substantive Due Process and Fundamental Rights to Life and Liberty

The United States and the New York State Constitutions guarantee substantive due process rights to life and liberty which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

The absence of any effective exemption to the Order or the Resolution denies Plaintiffs-Petitioners and their children of these rights to life and liberty.

It is a deprivation of the right to liberty, of both Plaintiffs-Petitioners and their children, to coerce a parent, under threat of a violation and civil punishment, to inject their child with a product when their informed decision, based on review of the existing literature regarding this product, their religious beliefs, and their intimate knowledge of their child, including the child's medical and familial history, is to not inject their child with this product.

Threatening a violation and civil punishment upon the refusal to inject a product that a parent has not consented to, and where the unrebutted science reflects it will increase mortality, infringes upon Plaintiffs-Petitioners' and their children's substantive right to life. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005) (medical science is "a field bereft of complete and direct proof of how vaccines affect the human body.").

B. Fourth Amendment

The Fourth Amendment to the United States Constitution, as well as the New York State Constitution, guarantee Plaintiffs-Petitioners the right “to be secure in their persons...against unreasonable searches and seizures.”

It is a deprivation of the right to protection from an unreasonable seizure to force an injection by piercing the skin in order to inject a product that was licensed without inadequate clinical trials. It is an unreasonable seizure of one’s person and one’s naïve immune system when a parent’s informed decision – based on review of the existing literature regarding this product, their religious beliefs, and their intimate knowledge of their child, including the child’s medical and familial history – is to not inject their child with this product.

Threatening a violation and civil punishment upon the refusal to inject a product that a parent has not consented to, and one for which the unrebutted record reflects an increased risk of mortality, infringes upon Plaintiffs-Petitioners’ and their children’s right to freedom from unreasonable seizure.

C. Excessive Fines

Both the United States and New York Constitutions prohibit excessive fines. “The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.” *United States v. Bajakajian*, 524 U.S. 321, 334 (1998).

The offense alleged here is the refusal of parents to inject their child with a product that a parent has not consented to, and one for which the record reflects will increase mortality, was not proven safe prior to licensure, and has numerous serious post-licensure adverse reactions. The mandate is not related to any privilege the parents or the children wish to enjoy; it is quite plainly

a mandate for them to simply continue existing in their homes with their families. The civil penalty – here, a fine of \$1,000 – is a hefty one for Plaintiffs-Petitioners who are working-class families and generally live paycheck to paycheck. The fine bears no relationship to the gravity of the offense: existing in their homes without injecting their children.

D. Unenumerated Rights

The Ninth Amendment to the United States Constitution guarantees that “the enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.”

1. The Right to Privacy

One of those unenumerated rights retained by the people is the right to privacy. Plaintiffs-Petitioners were issued Summonses at their homes – some with police officers delivering them, others with Summonses taped to their doors for all to see – alleging a violation for a private choice made by their families or in consultation with their doctors or religious leaders.

The Commissioner’s Order and the Resolution invaded that privacy, made Plaintiffs-Petitioners’ children’s vaccination statuses widely known, and attempted to commandeer the private decisions of these families.

Violating Plaintiffs-Petitioners’ right to privacy in their medical and religious decisions is a violation of the Ninth Amendment.

2. The Right to Informed Consent

Holding the Plaintiffs-Petitioners in violation for simply existing in their homes in the state in which they were born and for not injecting their children with a product that is not medically appropriate against their informed consent violates additional unenumerated constitutional rights, including the right to informed consent under the New York State Constitution and the United

States Constitution. It further violates the long upheld constitutional rights to parental choice and bodily integrity under the New York State Constitution and the United States Constitution.

The United States Constitution and the New York State Constitution guarantee the right to informed consent prior to administering a medical procedure. This right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

Informed consent requires that an individual be informed of the risks and benefits of a medical procedure and then be provided the uncoerced discretion to decide whether to consent to the medical procedure. Plaintiffs-Petitioners have reviewed the risks and benefits of the MMR and, based on that review and their intimate knowledge of their child, including their child's medical and family history, cannot consent to injecting this product into their children.

Threatening violations and civil penalties upon the refusal to inject a child with MMR where the child's parent has made an informed decision to not administer this product to their child infringes upon the well-established and valuable right to informed consent.

3. The Right to Parental Choice

The United States Constitution and the New York State Constitution guarantee the recognized right to parental choice, which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means.

Coercing a parent to vaccinate their child by threatening violations and civil penalties upon the refusal to inject the MMR, where the child's parent has chosen to not administer this product to their child, infringes upon their protected right to parental choice. *See Troxel v. Granville*, 530 U.S. 57, 65-66 (2000) ("The Fourteenth Amendment's Due Process Clause has a substantive component that 'provides heightened protection against government interference with certain fundamental rights and liberty interests ... including the fundamental right of parents to make

decisions concerning the care, custody, and control of their children”); *see also Parham v. J.R.*, 422 U.S. 584, 602 (1979) (a child is not a “mere creature of the State”).

4. The Right to Bodily Integrity

The United States Constitution and the New York State Constitution guarantee the right to bodily integrity. That right cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. *See, e.g., Rivers v. Katz*, 67 N.Y.2d 485, 494 (1986) (“fundamental right to make decisions concerning one’s own body”); *Blouin ex rel. Estate of Pouliot v. Spitzer*, 356 F.3d 348, 359 (2d Cir. 2004) (“fundamental right to bodily integrity”).

Plaintiffs-Petitioners are each fully competent and able to make decisions based on the best interests of their child. Based on their intimate knowledge of their child, including their child’s individual medical and familial histories, their religious beliefs, and their knowledge regarding the MMR, Plaintiffs-Petitioners and their children oppose injecting this product into their bodies.

Threatening violations and civil penalties by way of the Commissioner’s Order and the Resolution conditioned upon the injection of MMR, when the child and the child’s parents object to this injection, infringes upon the right to bodily integrity.

E. First Amendment Right to Free Exercise of Religion

The First Amendment to the United States Constitution unequivocally protects the right to the free exercise of religion. Likewise, the New York State Constitution provides that the free exercise of religion “shall forever be allowed in this state to all mankind.”

The free exercise clauses recognize the right of each person to engage in the free exercise of his or her religion and not to be compelled to engage in affirmative acts which violate their

religious beliefs. A key feature of this right is that it grants a religious individual an exemption from statutes or regulations which impose a burden on his or her beliefs.

Many of the Plaintiffs-Petitioners have sincerely held religious beliefs which prevent them from engaging in an act that they believe will harm their children.²⁶

The research has not yet been done to know which children are susceptible to be seriously injured or die from this product. Plaintiffs-Petitioners' informed assessment is that the risk of serious injury or death from this product to their child is greater than the risk of serious injury or death from measles and hence, administering this product to their child violates their religious beliefs.

At the time of the supposed violations, many of the Plaintiffs-Petitioners held statutorily protected religious exemptions from vaccinations from their children's schools.

Mandating an injection that directly contradicts Plaintiffs-Petitioners' religious beliefs is compelling them to act in a manner that plainly violates their right to freely exercise their religion; both the United States and the New York State Constitution protect Plaintiffs-Petitioners in refraining from an action that their religious beliefs prevent them from taking.

Indeed, Plaintiffs-Petitioners were held in violation for simply existing in their homes, with their families, in the state that God created them.

²⁶ Plaintiffs-Petitioners that hold religious beliefs against vaccination are Plaintiffs-Petitioners Ascher Berkowitz, Chava Biederman, Israel Fishman, Judith Fried, Malka Friedman, Chanie Fulop, Rachel Guttman, Simon Josef, and Malky Roth-Tabak.

CONCLUSION

Based on the foregoing, Plaintiffs-Petitioners respectfully requests that the Court grant the relief requested in their Verified Petition.

Dated: August 24, 2020

SIRI & GLIMSTAD LLP



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Counsel for Plaintiffs-Petitioners

office copy

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----- X

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

-against-

Department of Health and Mental Hygiene of the City Of
New York,

Defendant-Respondent.

**NOTICE OF CROSS-
MOTION TO DISMISS**

Index No. 156722/2020

Edmead, J.
IAS 35

----- X

Motion by: Defendant-Respondent Department of Health and
Mental Hygiene of the City of New York, by James
E. Johnson, Corporation Counsel of the City of New
York

Date of Return: February 16, 2021, at 9:30 am or as soon thereafter
as counsel can be heard.

Location of Return: New York County Supreme Court Motion Support,
Room 130, 60 Centre Street, New York, NY.

Supporting Papers: The Affirmation of LOUISE MOED, dated January
4, 2021, and the exhibits annexed thereto; and upon
all of the proceedings heretofore had herein.

Relief Requested: An Order, pursuant to CPLR § 3211(2) and 7804(f),
dismissing the proceeding for failure to state a cause
of action, and for such further relief as this Court
may deem just and proper.

Further, in the event that the Court denies this cross-
motion, the undersigned respectfully requests
permission to serve an answer within forty-five (45)
days of service of notice of entry of any such order.

Answering Papers:

Pursuant to CPLR 2214(b) and 2215, answering papers, if any, are required to be efiled at least seven days before the return date of this cross-motion.

Dated: New York, New York
January 4, 2021

JAMES E. JOHNSON
Corporation Counsel of the
City of New York
Attorney for Defendant-Respondent

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----- X

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

-against-

Department of Health and Mental Hygiene of the City Of
New York,

Defendant-Respondent.

----- X

**AFFIRMATION IN
SUPPORT OF
DEFENDANT’S CROSS-
MOTION TO DISMISS**

Index No. 156722/2020

Edmead, J.
IAS 35

LOUISE MOED, an attorney admitted to practice law before the courts of the State of New York, affirms the following to be true pursuant to CPLR 2106 and under the penalties of perjury:

1. I am an Assistant Corporation Counsel in the Office of James E. Johnson, Corporation Counsel of the City of New York, attorney for Department of Health and Mental Hygiene of the City of New York (“DOHMH” or the “Department”).

2. I am familiar with the facts and circumstances of the instant proceeding-action based upon records maintained by agencies of the City of New York, public documents, and upon statements of City staff.

3. DOHMH hereby cross-moves to dismiss the instant “Article 78 and Declaratory Judgment Petition” (hereinafter the “petition”) in its entirety for failure to state a cause of action.

4. Petitioners challenge the determinations rendered against each of them at the New York City Office of Trials and Hearings (“OATH”) Hearings Division that found them in violation of an April 9, 2019 Order of the DOHMH Commissioner (the “Order”) and the

subsequent April 17, 2019 Board of Health Resolution that continued that Order (the “Resolution”).¹ Petitioners argue that the determinations were arbitrary, capricious, and contrary to law. However, petitioners concede herein that they were indeed in violation. They did not attempt at OATH to disprove DOHMH’s allegations that they were in violation of the explicit mandates of both the Order and the Resolution. Rather, they raised various defenses to the charges that were not valid, and did not in any way attempt to establish that they were not in violation.

5. Petitioners also challenge the determinations rendered against each of them by disputing the validity of the medical science that provided the foundation for the Order and the Resolution, arguing that the summonses should have been dismissed at OATH in the interest of justice. Given that the Department was acting upon accepted medical science and the national medical standards for combatting measles, and that petitioners were relying on non-mainstream disputes with the national medical standards that are not widely accepted by the medical establishment, their challenge fails herein as a matter of law.

RELEVANT LAW

New York City Charter

6. New York City Charter § 556 provides, in relevant part, as follows:

§ 556 Functions, powers and duties of the department [of Health and Mental Hygiene].

Except as otherwise provided by law, the department shall have jurisdiction to regulate all matters affecting health in the city of New York and to perform all those functions and operations performed by the city that relate to the health of the people of the city The jurisdiction of the department shall include but not be limited to the following:

¹ Petitioners erroneously allege that the determinations were rendered by respondent, *i.e.*, DOHMH, and fail to name OATH as a respondent.

(a) General functions. (1) Enforce all provisions of law applicable in the area under the jurisdiction of the department for the preservation of human life, for the care, promotion and protection of health. . . . ;

(2) supervise the reporting and control of communicable and chronic diseases and conditions hazardous to life and health; exercise control over and supervise the abatement of nuisances affecting or likely to affect the public health.

* * *

The New York City Administrative Code

7. Administrative Code § 17-142 defines a public health “nuisance” in relevant part, as follows:

The word “nuisance” shall be held to embrace public nuisance, as known at common law or in equity jurisprudence; whatever is dangerous to human life or detrimental to health; . . . and whatever renders the air or human food or drink, unwholesome. All such nuisances are hereby declared illegal.

The New York City Health Code²

8. Health Code § 3.01 provides General Powers of the Department. Health Code § 3.01(c) authorizes DOHMH to “take such action as may become necessary to assure the maintenance of public health, prevention of disease, or safety of the City and its residents.”

9. Health Code § 3.01(d) states, in part: “Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health and safety of the City and its residents. . . . provided

² The New York City Health Code is published as part of Title 24 of the Rules of the City of New York.

that any such exercise of authority or power shall be effective only until the next meeting of the Board....”

10. Health Code § 3.05(a) states that “[n]o person shall violate an order of the Board, Commissioner or Department. Pursuant to Health Code § 3.11, violations of the Code are subject to civil enforcement, punishable by a civil penalty. Pursuant to Health Code § 3.12, the Administrative Tribunal established by the Board of Health pursuant to City Charter § 558 is now operated within OATH, and notices of violation or summonses that are issued by DOHMH are adjudicated at OATH.

**New York City Office of
Administrative Trials and Hearings**

11. Chapter 45-A of the City Charter establishes the New York City Office of Administrative Trials and Hearings (“OATH”). City Charter § 1049-a establishes the Environmental Control Board (“ECB”) as part of OATH. ECB, or the Board, consists of 13 members, including the commissioners of six city agencies - Environmental Protection, Sanitation, Buildings, Health and Mental Hygiene, Police, and Fire. The Board is chaired by the chief administrative law judge of OATH. *Id.* In addition, pursuant to the City Charter, the Board consists of six people to be appointed by the Mayor who are not otherwise employed by the City and who have broad general experience in several areas, including water pollution control, air pollution control, noise pollution control, real estate, and business, as well as a member of the general public. *Id.*

12. Effective August 7, 2016, 48 RCNY § 6-02 brought the Environmental Control Board (“ECB”) under the auspices of the OATH Hearings Division, which is the tribunal charged with adjudicating summonses formerly returnable at the ECB. ECB now consists of thirteen members, who, among other things, preside over the OATH Appeals Unit and act as

final arbiters on all appeal decisions. As such, the Appeals Unit decision referenced throughout this Memorandum of Law was reviewed, analyzed, and affirmed by the ECB (the Board).

RELEVANT FACTS

A. The 2018-2019 Measles Epidemic in Williamsburg

13. Beginning in early October 2018, there was an active measles outbreak in New York City. By April 2019, the outbreak had resulted in over 300 cases of this vaccine-preventable disease. The vast majority of these cases were among residents in Williamsburg zip codes 11205, 11206, 11211, and 11249.

14. The danger of measles and the public health measures being taken by respondent to combat it in New York City are set forth in the annexed affirmation of Dr. Demetre Daskalakis dated April 16, 2019 (annexed hereto as Exhibit 1) that was written and submitted during the epidemic in a case that contemporaneously challenged the Order, *C.F. v. NYC Dept. of Health and Mental Hygiene*, Kings Co. Index No. 508356/2019. A decision dismissing the matter is published at 2019 NY Misc LEXIS 1914 (Sup. Ct. Kings Co. April 18, 2019). That dismissal has just been upheld by the Appellate Division, Second Department, in a decision dated December 23, 2020 (appended to respondent's accompanying Memorandum of Law as Appendix A).

B. DOHMH Outreach Efforts to Quell the Outbreak

15. As is set forth in the Daskalakis Affirmation, the Department tried multiple strategies to end the outbreak. Due to low vaccination rates in the four Williamsburg zip codes, the outbreak continued despite the Department's outreach efforts. The Commissioner determined that the presence of people in Williamsburg lacking the Measles-Mumps-Rubella ("MMR") vaccine created an unnecessary and avoidable risk of continuing the outbreak.

C. The DOHMH Commissioner's April 9, 2019 Order

16. As a result of the continued outbreak, on April 9, 2019, Oxiris Barbot, M.D., then Commissioner of DOHMH ("Commissioner"), issued an Order that ordered vaccination with the MMR vaccine for residents of four zip codes located within the Williamsburg neighborhood of Brooklyn, New York (the "Order," annexed as Exhibit 2), unless they could establish that they had immunity to measles, or that they should be medically exempted from the requirement. The Order did not mandate that people be forcibly vaccinated without consent. Rather, a failure to comply with the Order would subject an individual to civil penalties.³ Pursuant to Health Code § 3.01(d), the Order was to remain in effect until the Board of Health was to meet on April 17, 2019, at which time the Board would determine whether the vaccination requirement would be continued or rescinded.

17. The Order read as follows:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person

³ While the Order warned that a violation of Health Code §3.05 is potentially a criminal offense, the Department enforced the Order only civilly.

coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect t or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health code, I am authorized to declare a public health emergency and issue orders and take actions that I deem necessary for the health and safe ty of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health o to the life or health of any individual... or

...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED, that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS HEREBY ORDERED, that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene... If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization

D. The Board of Health's April 17, 2019 Resolution

18. On April 17, 2019, the Board of Health issued a Resolution (the “Resolution,” annexed as Exhibit 3) ordering all non-immune people who lived, attended school, or worked in the four Williamsburg zip codes to vaccinate themselves and their children, unless they could not be vaccinated for medical reasons. Those who failed to vaccinate faced a civil

penalty, unless they could demonstrate a valid medical exemption. The Resolution reiterated several “Whereas” clauses directly from the Order, and read as follows:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 111206, 11211 and 11249 (the “affected zip codes”); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine, unless such person or, for a child, such person’s parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner’s exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, to Board of Health regards the aforesaid reports of over cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement;

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)

E. The Civil Enforcement Process

19. In April, May, and June 2019, the Department issued civil summonses returnable in OATH's Hearings Division to some parents for failure to comply with the MMR vaccination requirement with respect to their children who fell within the parameters of the

Order.⁴ In each summons, the person issuing the summons alleged that a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in New York City and is required to be updated by medical providers, found no record of the child who was the subject of the summons having been vaccinated against measles or having submitted proof of immunity or the need for a medical exemption. Attached to each summons was a document entitled "Frequently Asked Questions" (FAQ," annexed as Exhibit 4) that set forth facts about the dangerous nature of measles, the safety and efficacy of the MMR vaccine, and instructions for how to either prove immunity to measles or apply for a medical exemption if the MMR vaccine was contraindicated for a particular child.

20. At issue herein are eleven summonses, each of which was issued by respondent to one of the eleven petitioners herein for failure to have the MMR vaccine administered to one of their children who fell within the parameters of the Commissioner's Order. The petitioners were each found by an OATH Hearing Officer to be in violation, and those determinations were upheld by the OATH Appeals Unit.

F. Hearings in the OATH Hearings Division

21. Hearings took place before OATH Hearing Officer David Leung. Attorney Aaron Siri, whose firm represents the petitioners herein, represented those eleven

⁴ The summonses were issued by the following DOHMH staff members, all of whom are referred to at OATH as the "issuing officer":

Jane Bedell, Medical Director, Bronx Neighborhood Health Action Center (now retired);
Gerald Cohen, Director of Clinical Affairs, Division of Mental Hygiene;
Torian Easterling, First Deputy Commissioner and Chief Equity Officer;
Pooja Jani, Preventative Medicine Resident Fellow, Bureau of Mental Hygiene Community Engagement, Policy and Practice, Division of Mental Hygiene;
Deborah Kaplan, Assistant Commissioner, Bureau of Maternal, Infant, & Reproductive Health, Division of Family & Child Health (now retired).

petitioners at the OATH hearings, where they were respondents and were referred to as such in the OATH documents annexed herein. To avoid confusion, they will continue to be referred to herein as petitioners except when directly quoting an OATH document.

22. Petitioners annexed to their petition the following documents pertaining to each petitioner:

Summonses (Ps' Ex. F, NYSCEF Doc. No. 9)

OATH Appeal Decisions (Ps' Ex. G, NYSCEF Doc. No. 10).

23. For the Court's convenience, respondent annexes the documents relevant to each petitioner in separate exhibits, each containing the summons, the transcript, the Hearings Division decision, the appeals brief, and the Appeals Unit decision for that petitioner.

24. None of the petitioners appeared at the OATH hearings to testify on their own behalf but, rather, were represented by their attorney.

25. The Hearing Officer found each of the petitioners in violation. The decisions each contained the following findings that were common to the defenses interposed in the first hearing that took place, the hearing on the summons issued to petitioner Tabak, and subsequently deemed to be interposed in each hearing (see ¶ 37 hereinbelow regarding the Tabak hearing), as well as individualized findings addressing the particular defenses raised by each petitioner (set forth separately hereinbelow in the summaries of each hearing, ¶¶ 39-59).

Malky Tabak hearing (Exhibits 5 and 6)

26. The first such hearing was on the summons issued to petitioner Malky Tabak. The transcript of that hearing is annexed separately from the other Tabak documents as Exhibit 5. An agreement was made that the arguments petitioners' attorney was making in this first hearing and the evidence he was submitting would be deemed "transferred over" to

subsequent hearings (Tr 123),⁵ thus constituting a common defense for all eleven petitioners (Tr 205-06).

27. The attorney put on the record that he was not waiving the appearance at the hearing of the issuing officer. He asserted the right to have the issuing officer testify about how he or she obtained the information that the child that was the subject of each summons had not been immunized and whether the MMR vaccine was medically appropriate for that child (Tr 6-8).

28. DOHMH General Counsel Thomas Merrill stated that that the summonses were issued after checking the Central Immunization Registry (Tr 8-9) and that DOHMH's medical witness, Dr. Jennifer Rosen, Director of Epidemiology and Surveillance for DOHMH's Bureau of Immunization, could testify about the Department's outreach efforts, explain the medical necessity of the administration of the MMR vaccine, that the MMR vaccine is safe and medically appropriate for the vast majority of people, and that there is a review process for someone seeking a medical exemption where immunization would be medically inappropriate, but there was no indication that the child who was the subject of the Tabak summons had one of the rare conditions that would make the vaccine medically contraindicated for that child (Tr 11-12). In addition, DOHMH counsel pointed to the FAQ that was served with the Commissioner's Orders, which included information about the provision for submitting either proof of immunity or proof in support of a medical exemption (Tr 15). He stated that the Department's immunization registry had been checked for this child, and it contained no proof for this child of immunization. Nor did Department records contain documentation of immunity or medical exemption. (Tr 19-20). When questioned by petitioners' attorney as to whether she knew

⁵ References to transcripts are denoted by "Tr" followed by the relevant page numbers.

whether the subject child had medical contraindications against the MMR vaccine, Dr. Rosen testified that Department of Health records did not contain documentation of any contraindication for the subject child to receive the MMR vaccine and that the petitioner was notified that if there were medical contraindications, documentation should be submitted (Tr 98-103).

29. OATH Hearing Officer Leung pointed to OATH's liberal hearsay rules, and ruled that the hearing would go forward without the issuing officer. His basis was that what the issuing officer wrote on the summons established the *prima facie* case (Tr 12-13).

30. Petitioners' attorney first moved to dismiss the summons on the basis that the April 9, 2019 Order expired when the Board of Health met on April 17, 2019, that the Board did not say it was "continuing or rescinding" the Order, and thus the Tabak summons that alleged failure to comply with the Order on April 21, 2019 was alleging violation of an Order no longer in existence. DOHMH General Counsel pointed to Health Code § 3.05, which made it a violation to violate any order, and that the Resolution was also an order. The Board of Health continued the Commissioner's Order by its Resolution, and slight differences in the language used did not change the validity of the Board of Health's Order. There was extensive oral argument on this issue (Tr 22-63).

31. Petitioners' attorney also pointed to the fact that the Order contained a section entitled "Warning," which recited the possible consequences of failing to comply with the Order, which, pursuant to Health Code § 3.05, can be charged as a misdemeanor and can lead to forfeiture, criminal fines, or imprisonment (Tr 42-44), which remedies are not provided for in the Resolution. DOHMH's attorney pointed to the fact that that language about possible consequences for violating a Health Department Order was included in all orders, and that the

Department's intention was to enforce the vaccination order civilly (Tr 49). He also pointed to the fact that the Resolution comprised an order (Tr 50).

32. Petitioners' attorney argued that the summons wasn't proper because the Board of Health's Resolution wasn't published for three days prior to the issuance of the summons as set forth in Admin. Code § 17-148(c) (Tr 64). The Resolution was published on April 22 through 24, but the summons was issued to Tabak on April 21, thus providing less notice to the respondent than was mandated. DOHMH's General Counsel argued that the Order was continued by the Resolution and was still in effect on April 21. He further argued that if petitioners' counsel took the position that the meeting of the Board of Health on April 17, 2019 and the adoption of the Resolution extinguished the Order and also argued that the Resolution was not in effect until April 24, he was arguing for leaving a gap in the Department being able to address the health emergency (Tr 66-68). The argument returned to the issue of whether the Board of Health Resolution continued the Order (Tr 68-76). DOHMH's General Counsel argued that the remedial action of mandating vaccination continued to be in effect, whether by the Commissioner's Order or by the Board of Health's Resolution (Tr 76-78) and he pointed to the Resolution's own language that it was to take effect immediately.

33. Petitioners' attorney then presented constitutional arguments, while acknowledging that those issues were beyond the jurisdiction of OATH (Tr 78-80). He raised the issue of the right to informed consent, parental choice, bodily integrity, free exercise of religion, substantive due process, procedural due process, the Ninth Amendment to the federal constitution, and the protection against cruel and unusual punishment. He put on the record his assertion that the Commissioner's Order was in excess of jurisdiction, an error of law, arbitrary and capricious, and an abuse of discretion (Tr 80). He also said he sought to depose the

Commissioner and a member of the Board of Health, his purpose being to challenge the Commissioner with respect to the safety and efficacy of the MMR vaccine (Tr 80-82). The Hearing Officer pointed out that DOHMH physician Dr. Rosen was at the hearing prepared to testify as a representative of the Department. DOHMH's General Counsel argued that a deposition would not address issues of constitutionality. He pointed out that the Commissioner's Order had been upheld by a court in litigation challenging the Order.⁶ He also pointed to the fact that a recent court decision upheld New York State's recent elimination of the religious exemption from the mandatory vaccine requirements for school attendance (Tr 84-85)⁷ DOHMH's medical witness doctor could answer questions about measles and the vaccine (Tr 86). The Hearing Officer denied petitioners' attorney's application for depositions (Tr 116-17).

34. Petitioners' counsel began his questioning of DOHMH's witness, Dr. Rosen (beginning at Tr 86 and continuing throughout). He asked her questions about the National Childhood Vaccine Injury Act of 1986 and about the immunity from suit supposedly given to Merck, the manufacturer of the MMR vaccine. He asked her basic biology questions about viruses. The Hearing Officer interrupted petitioners' counsel and asked him to ask relevant questions (Tr 92-93). Dr. Rosen answered questions as to how the Department became aware of the child whose parent was the subject of the summons (the "subject child"): from the medical facility that learned of this particular child's exposure to measles (Tr 94-97). She also answered general questions about the completeness of the Department's Citywide Immunization Registry (Tr 96-97).

⁶ *C.F. v. NYC Dept. of Health and Mental Hygiene*, 2019 NY Misc LEXIS 1914 (Sup. Ct. Kings Co. April 18, 2019), dismissed by Appellate Division, Second Department decision dated December 23, 2020.

⁷ *F.F. v. State of New York*, 66 Misc3d 467 (Sup. Ct. Albany Co. 2019).

35. Through further questions to Dr. Rosen and further colloquy between petitioners' counsel and the Hearing Officer, petitioners' attorney implied that it was the Department's burden to find out if a particular child had contraindications to the MMR vaccine. Dr. Rosen kept pointing to the lack of any documentation to that effect having been submitted by a medical provider regarding the subject child, and that people to whom summonses were issued were notified that they could submit documentation of a contraindication to the MMR vaccine (Tr 98-105). There was further colloquy on petitioners' attorney's argument that the MMR vaccine was generally not medically appropriate. The Hearing Officer stated that the current hearing was not a full-blown trial and that the attorney could present a defense comprised of evidence that the subject child was medically exempt from the vaccine but that such a defense would not be established by asking Dr. Rosen questions (Tr 103-118). He asked petitioners' attorney whether he had documentation that the subject child was medically exempt from the MMR vaccine or was already immune. Petitioners' attorney then pointed to the box of documents that he had brought to the hearing (Tr 119). In response to the Hearing Officer's question, he said that his offer of proof was that the risks of the MMR vaccine outweigh its benefits (Tr 119 20).

36. The Hearing Officer then asked Dr. Rosen what would warrant medical exemption. Dr. Rosen said that there were standard criteria as to what are contraindications for the MMR vaccine, and further that it would not be a parent's decision but would come from a medical provider based on the national standards (Tr 125-27). The Hearing Officer asked Dr. Rosen to state some of the medically exempt conditions. Dr. Rosen mentioned pregnancy, being severely immunocompromised, *e.g.*, in the process of receiving chemotherapy or cancer treatment, a documented severe, life-threatening allergic reaction to a vaccine component, *e.g.*,

an anaphylactic reaction, not merely a rash (Tr 126-27). She further testified that, since no documentation of a contraindication had been submitted for the subject child, DOHMH was left to assume that the child did not have any medical contraindications (Tr 127). She also said that medical contraindications to the MMR vaccine were extremely rare (Tr 127). When asked by petitioners' attorney whether the MMR vaccine could cause brain damage, Dr. Rosen testified that it was extremely rare and that the safety of the vaccine was closely monitored and that millions of doses of the vaccine had been given (Tr 127-28). Petitioners' attorney pointed to New York City Charter § 1049(5)(a)⁸ as a basis for the Hearing Officer to dismiss the summons in the interests of justice. The Hearing Officer responded by directing respondents' attorney to restrict his questions to the issue of medical exemption for the subject child. (Tr 129-132). Petitioners' attorney then introduced into evidence petitioners' Exhibit 2, an informational statement from the United States Centers for Disease Control (the "CDC") about the MMR vaccine, which petitioners' attorney argued supported dismissal of the summons in the interests of justice (Tr 134-39), followed by colloquy between petitioners' attorney and the Hearing Officer as to whether the evidence the attorney wished to submit and the examination he wished to conduct were relevant to the summons being adjudicated. Petitioners' attorney then submitted into evidence Exhibits 4 through 45, which consisted of various documents that, he argued, called into question the safety and efficacy of the MMR vaccine (Tr 145-206). He also questioned Dr. Rosen about how the MMR vaccine was originally approved, to which the Hearing Officer objected that these questions were not relevant to the summons about which he had to make a determination (Tr 141-45). There was extensive colloquy and argument by petitioners' attorney about the contents of each exhibit and how it challenged the safety and

⁸ The transcript records this reference by petitioners' attorney as 104.9.5.

efficacy of the MMR vaccine and questioned the dangerousness of becoming ill with measles. The Hearing Officer asked questions about the connection between the documents and the summons (Tr 145-206).

37. DOHMH's General Counsel pointed to statements in petitioners' Exhibit 2 (a CDC publication about the MMR vaccine), that getting the MMR vaccine was much safer than getting measles, mumps, or Rubella disease (the three diseases against which the MMR immunizes) and that severe allergic reactions to the MMR vaccine were estimated to occur in response to approximately one in a million doses. (Tr 200-01).

38. A hearing was held on each of the remaining ten summonses. The exhibits introduced at the Tabak hearing were deemed to be part of each subsequent hearing.⁹

39. The Hearing Officer rendered decisions on each of the summonses. They all contained the following findings from the Tabak decision (with some minor differences in wording):

Respondent [referring to the petitioner who was the subject of the particular hearing] made a variety of constitutional and scientific arguments and challenges to the validity, efficacy and safety of the MMR vaccine and to the fundamental fairness of the summons and Petitioner's [DOHMH's] authority to mandate vaccination. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).

Petitioner [DOHMH] responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues.)^[10]

⁹ The hearings are presented in the order in which the hearings took place.

¹⁰ *C.F. v. NYC Dept. of Health and Mental Hygiene*, 2019 NY Misc LEXIS 1914 (Sup. Ct. Kings Co. April 18, 2019).

I find that Respondent's [petitioner's] constitutional and scientific arguments are beyond the scope of this hearing, and as such, I made no findings as to Respondent's [petitioner's] evidence or arguments in these areas.

I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.

40. Each decision also contained specific findings relevant to each petitioner, where there were such particular defenses to be addressed.

Malky Tabak (Exhibit 6)

41. The Hearing Officer's decision found that petitioner Tabak was in violation and pointed to the lack of a doctor's note or medical records demonstrating a medical exemption.

Beila Englander (Exhibit 7)

42. Petitioners' attorney argued that petitioner Englander had nine children who were vaccinated and that the child who was the subject of the summons was the only child of petitioner, the child's mother, who wasn't vaccinated. Petitioner did not believe that the child was immunologically capable of handling the vaccine without having a serious reaction (Tr 14-15). DOHMH's General Counsel said that no documentation had been submitted to the Department in this regard (Tr 15-16). Respondent's attorney declined the Hearing Officer's offer of an adjournment to produce documentation, asserting instead that the mother knew the child best and it was the Department's burden to show that the vaccine was safe and effective with respect to the subject child (Tr 15-17).

43. The Hearing Officer's decision found that petitioner Englander was in violation for failing to provide a defense.

Baila Hauer (Exhibit 8)

44. Petitioners' attorney made two arguments regarding this summons on behalf of petitioner Hauer. First, petitioner challenged the fact that her father was served with the summons in his first floor apartment, while she lived on the second floor (Tr 6-9). Also, she pointed to the fact that the MMR is not licensed to be administered in children who are under 12 months of age, which was the case of the subject child (Tr 9-10). DOHMH submitted an affidavit of service that recited that the father said he'd give the summons to petitioner, and also recited that it was mailed (Tr 7-8). Dr. Rosen testified that the Advisory Committee on Immunization Practices, which sets the national recommended schedule for immunizations recommends that the MMR vaccine can be administered to children ages six to eleven months during an outbreak (Tr 10-11).

45. The Hearing Officer's decision found that petitioner Hauer was in violation. He stated that substitute service upon petitioner's father satisfied the service requirements in the OATH rules. He also relied on Dr. Rosen's testimony that the MMR vaccine is appropriate for a child six months and older during an outbreak.¹¹

Chava Biederman (Exhibit 9)

46. Petitioners' attorney submitted an affidavit that petitioner Biederman resided on the 3rd floor, not the 2nd floor as stated on the summons, and that she had not been personally served. Thus, to the extent that the summons alleged that the violation took place at the address on the summons, there was no violation there because petitioner didn't reside there (Tr 6). However, in response to a question by Hearing Officer Leung, the attorney said that

¹¹ The Hearing Officer incorrectly paraphrased Dr. Rosen's testimony on this point as "older than six months."

petitioner did not deny having received the summons by mail (Tr 6-7). In response, DOHMH counsel argued that the floor was not material to the violation, that the material element was that she was in Brooklyn. The summons reached her at that building, and the fact that she lived on a different floor was immaterial in terms of her having violated the Order (Tr 9-11).

47. The Hearing Officer's decision found that petitioner Biederman was in violation, as the incorrect floor number on the summons did not affect her right to notice of the violation or to receive a fair hearing.

Rachel Guttman (Exhibit 10)

48. Petitioners' attorney interposed no defenses on behalf of petitioner Guttman beyond the arguments made in the Tabak hearing (Tr 6).

49. The Hearing Officer's decision found that respondent was in violation, stating that the constitutional and medical arguments in the Tabak hearing were beyond the scope of the hearing.

Ascher Berkowitz (Exhibit 11)

50. Petitioners' attorney submitted what he referred to as "a declaration" from the mother of the child who was the subject of the summons that the child was recovering from eye surgery on the date the summons was issued, June 4. According to petitioners' attorney, the child's pediatrician was afraid to write to the Department that the child should not be vaccinated. The mother's document was accepted into evidence (Tr 6-7). DOHMH's attorney pointed to the fact that there was ample time after the Order was issued in April for the child to be vaccinated before having eye surgery (Tr 7-12). He pointed to the requirement for a doctor's note in order to obtain a medical exemption under State law for school admission, and thus "pediatricians have to give notes" (Tr 7-8). Dr. Rosen then said that, according to the national standards, eye surgery

is not a contraindication for the MMR vaccine, and perhaps that is why the pediatrician would not write a note (Tr 8-9). In response to petitioners' attorney suggesting that a moderate illness could be a "precaution" against being given the MMR vaccine, Dr. Rosen said that it would have to be an acute illness and that surgery is not a contraindication (Tr 9).

51. The Hearing Officer's decision found that petitioner Berkowitz was in violation and pointed to the lack of a doctor's note or medical records demonstrating a medical exemption.

Israel Fishman (Exhibit 12)

52. Petitioners' attorney made three arguments against the summons on behalf of petitioner Fishman. First, petitioner alleged that he did not get the summons in the mail (Tr 6-7). Second, petitioners' attorney asserted that petitioner did not vaccinate the subject child because an older sibling had medical issues that petitioner believed had been caused by the MMR vaccine (Tr 8-9). Third, petitioner had a religious objection to the MMR vaccine (Tr 12). DOHMH's attorney produced an affidavit showing mail service upon petitioner. DOHMH also pointed to the fact that petitioner presented no documentation from a medical provider presenting a basis for a medical exemption for the subject child, and that a sibling's supposed bad reaction to the vaccine was not a contraindication to other siblings being vaccinated (Tr 9-12).

53. The Hearing Officer's decision found that petitioner Fishman was in violation for failing to provide a defense. The petitioner admitted that the summons had been taped to the apartment door, and DOHMH's the certificate of service reflected proper mailing. Also, petitioner did not establish a medical exemption for the subject child.

Malka Friedman (Exhibit 13)

54. Petitioners' attorney made two arguments regarding this summons on behalf of petitioner Friedman. First, petitioner allegedly did not vaccinate the subject child because the subject child allegedly had a moderate acute illness on the summons date, June 4 (Tr 6). Also, petitioner asserted a religious objection (Tr 6-7). DOHMH's General Counsel pointed to the lack of a doctor's affidavit asserting the need for a medical exemption. He also pointed to the fact that there was ample time after the Order was issued in April and May for the child to be vaccinated before allegedly being ill on June 4. DOHMH General Counsel also said that religion was not a defense to the MMR vaccine Order (Tr 6-7).

55. The Hearing Officer's decision found that petitioner Friedman was in violation for failing to submit a doctor's note about the subject child's supposed illness, and also that there was no religious exemption defense.

Judith Fried (Exhibit 14)

56. Petitioners' attorney made four arguments regarding this summons on behalf of petitioner Fried. First, petitioner challenged service of the summons after 11pm (Tr 6-10). Second, petitioner challenged the fact that the MMR vaccine is usually prescribed for a child 12 months and over, and the subject child was an unspecified age under 12 months (Tr 11-12). Third, the subject child's sibling allegedly had had a moderate to severe adverse reaction to the vaccine (Tr 12). Finally, the petitioner had a religious objection to the vaccine (Tr 12). There was colloquy on whether there was an actual provision of law prohibiting service at night. No such provision was discovered. DOHMH witness Dr. Rosen testified that, during an outbreak, the national standard recommended that the MMR vaccine can be given to infants who are six to eleven months old (Tr 12-13). She also testified that a sibling's reaction is not a

recognized contraindication (Tr 13), and petitioner was free to submit documentation from a physician supporting a medical exemption for the subject child (Tr 13).

57. The Hearing Officer's decision found that petitioner Fishman was in violation for failing to provide a defense. The petitioner admitted that the summons had been taped to the apartment door, and DOHMH's certificate of service reflected proper mailing. Also, petitioner did not establish a medical exemption for the subject child.

Simon Josef (Exhibit 15)

58. Petitioners' attorney argued that the petitioner Josef had a religious objection to the MMR vaccine (Tr 5). DOHMH General Counsel responded that that objection did not affect the Order and the violation (Tr 6).

59. The Hearing Officer's decision found that petitioner Josef was in violation because there was no religious exemption defense.

Chanie Fulop (Exhibit 16)

60. Petitioners' attorney made three arguments regarding this summons on behalf of petitioner Fulop. First, petitioner didn't vaccinate the subject child because the MMR is not licensed to be administered in children who are under 12 months of age, which was the case of the subject child (Tr 5-6). Second, petitioner had a religious objection to the vaccine (Tr 6). Third, petitioner alleged that the summons was taped to the apartment door but not received by mail (Tr 6). Dr. Rosen testified about the recommendation that children between six and eleven months be vaccinated during an outbreak (Tr 7-8). The DOHMH General Counsel argued that there is no religious exemption to the Order (Tr 7). The DOHMH General Counsel also submitted an affidavit of service attesting to mailing (Tr 7).

61. The Hearing Officer's decision found that petitioner Fulop was in violation for failing to provide a defense. Petitioner had admitted that the summons was taped to the apartment door, and the certificate of service and mailing reflected proper mailing. In an outbreak, the MMR is appropriate for a child older than six months. Petitioner did not establish a medical exemption for the subject child, and a religious objection isn't a valid defense.

G. OATH Administrative Appeals

62. All of the petitioners sought administrative appeals at OATH. The briefs submitted for each appeal contained much material in common. Petitioners argued that the Order had expired as a matter of law when the Board of Health met on April 17, 2019, and that it had not been continued by the Board of Health Resolution adopted that day. Petitioners also argued that the petitioners were deprived of a fair hearing because the issuing officer was not present to be cross-examined, in particular about whether the subject child had any medical contraindications to being vaccinated. Petitioners also pointed to the various medical papers they had submitted at the hearing that challenged the safety and efficacy of the MMR vaccine and the medical establishment's consensus that it is dangerous to health to be infected with measles. The briefs also mentioned in passing the various defenses that had been raised by individual petitioners.

63. DOHMH submitted briefs, also containing much material in common as well as addressing the specific defenses interposed by each petitioner. DOHMH argued that the Resolution continued the Commissioner's exercise of power asserted in her Order, as evidenced by the fact that the Resolution repeated the main directive of the Commissioner's Order that people living in the 11205, 11206, 11211 and 11249 zip codes who had not been vaccinated against measles be vaccinated against measles unless they could demonstrate immunity or a

medical exemption, and that the differences in language used in the Order and Resolution did not affect the applicability of the Commissioner's Order or the Resolution to the summonses issued to petitioners. DOHMH further argued that the summonses provided reasonable notice to petitioners such as satisfied due process, and that the testimony of Dr. Rosen was sufficient to ensure fair hearings. DOHMH pointed to the City Charter provisions that prohibited the dismissal of the summonses "in the interest of justice," and further pointed out that the constitutional claims raised by petitioners were not properly before OATH. DOHMH pointed to case law supporting the proposition that service in the context of an administrative hearing can be proper even if there is a minor defect in service so long as the notice is reasonably calculated to make the parties aware of the proceeding so that they have an opportunity to be heard. DOHMH also pointed out that mere denial by an intended recipient of a mailing is not sufficient to overcome the presumption that properly addressed mail is received.

64. The OATH Appeals Unit issued appeal decisions sustaining the findings of violation against each petitioner.¹² In addition to containing findings regarding each petitioner's defenses, the decisions contained, in substance, the following material set forth in the decision on the Tabak appeal regarding the defenses interposed at the Tabak hearing on behalf of all petitioners:¹³

Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence.

* * *

¹² The Appeals Decisions refer to petitioners herein as "Respondents" and DOHMH as "Petitioner."

¹³ There are slight wording variations between the various decisions, each of which is annexed as part of the exhibit pertaining to each petitioner.

The issues on appeal are (1) [the specific defense(s) raised by that respondent]; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the [Issuing Officer] for cross-examination; and (3) whether Respondent established a defense to the charge.

* * *

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order requiring that any person living, working or residing in those ZIP codes who had not received the MMR vaccine be vaccinated within forty-eight hours of the Order being signed, unless such person could demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement. The Order further ordered that the parent or guardian of any such child older than six months of age should cause such child to be vaccinated within that forty-eight hour period unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019; the Order remained in effect at least until the BOH [Board of Health] met on April 17, 2019. As the summons in this case was dated after April 17, 2019, Respondent argues that it must be dismissed because by that date the Order had expired. That is not correct. The summons, which was issued on [date of summons], was based on an examination of Petitioner's records that took place on [date of examination set forth in each summons]; that examination provided uncontroverted evidence that the child was not vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child was subsequently vaccinated.

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, it was for Respondent

to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.⁹ There is no evidence in this record to show that Respondent offered any proof of immunity or any documentation that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds that the hearing officer's ruling that the [Issuing Officer's] appearance was not necessary for a fair hearing was reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁰ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician had personal knowledge of the same vaccination records examined by the [Issuing Officer] and was available to testify. As to Respondent's request for dismissal in the interests of justice pursuant to [New York City Charter] § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections raised are beyond the jurisdiction of the Tribunal.

⁹See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirements).

¹⁰See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

[The paragraphs addressing each individual petitioner's defenses are set forth below.]

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

Tabak: In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by

not having the [Issuing Officer] present for cross-examination, and that Respondent did not establish a defense to the charge.

Englander: [no individualized finding regarding this Respondent]

Hauer: Per 48 RCNY § 6-08(b)(1)ii), service of a summons may be made by mail. As there was uncontroverted testimony and documentation that the summons was mailed to Respondent, the Tribunal finds that service was proper. ...

Biederman: Petitioner is correct that the floor location of Respondent's apartment was not material to the charge. As Petitioner established Respondent's residence in one of the subject ZIP codes, and service by mail was not denied. The hearing officer properly did not dismiss the summons because of a possible error in the floor number.

Guttman: [no individualized finding regarding this Respondent]

Berkowitz: [no individualized finding regarding this Respondent]

Fishman: There is no evidence in this record to show that Respondent offered proof of immunity or documentation, such as a doctor's note, that that vaccination was medically inappropriate specifically for this child. It was not error for the hearing officer to credit the DOHMH physician's position that an adverse reaction by a sibling did not establish a medical exemption for the subject child.

Friedman: There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. Even if the child was ill on the day the summons was issued, the violation was established by the failure to vaccinate during the time specified in the Order.

Fried, Josef, and Fulop: There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child.

H. The Filing of the Instant Article 78-Declaratory Judgment Matter

65. On June 24, 2019, petitioners commenced the instant matter by e-filing what they denominated a “Verified Article 78 and Declaratory Judgment Petition” (the “petition”).^{14, 15} The petition sought the following relief:

- a) Declaring, pursuant to CPLR § 7803, that Defendant-Respondent acted arbitrarily, capriciously, and contrary to law by issuing its final determinations in the manner described herein;¹⁶
- b) Declaring, pursuant to CPLR § 3001 and all other grounds by which a state act can be declared unconstitutional, that the Commissioner’s Order and the Resolution violate the New York and United States Constitutions;
- c) Setting aside and vacating the Summonses;
- d) Awarding Plaintiffs-Petitioners reasonable attorney’s fees, costs and disbursements pursuant to CPLR § 8101, 42 U.S.C.A. § 1983, and other applicable statutory, common law or equitable provision, and that any defense as to the validity of the summonses is without merit.

¹⁴ The 29-page petition containing 94 paragraphs is not in compliance with CPLR 3014 in that numerous paragraphs contain argument rather than plain and concise statements, each containing a single factual allegation, regarding the administrative determinations being challenged herein. Contrary to CPLR 3013, numerous paragraphs throughout the petition contain allegations and arguments that are unrelated to the transactions that comprise the material elements of the causes of action in that they challenge national medical standards of care. Contrary to New York State’s Uniform Rules for Trial Courts § 202.8(c) that argument shall be set forth in briefs, the petition contains argument regarding the medical standards of care regarding measles that should have been set forth in plaintiffs’-petitioners’ memorandum of law.

¹⁵ Pursuant to CPLR 2214(c), respondent is not annexing a copy of the petition to its papers as an exhibit but respectfully refers the Court to NYSCEF Doc. Nos. 1-53.

¹⁶ Respondent, DOHMH, did not issue the determinations challenged herein. The determinations were issued by an OATH Hearing Officer and the OATH Appeals Unit. OATH was not named as a respondent herein.

I. The End of the Measles Epidemic in Williamsburg

66. As of mid-July 2019, no new cases of measles were reported to DOHMH. On September 3, 2019, two incubation periods having passed without a new case, DOHMH declared the end of the measles public health emergency. DOHMH's "2019 Health Alert #26: Update on Measles Outbreak in New York City" and a press release are annexed as Exhibit 17. Those documents recite that since the beginning of the outbreak in October 2018, 654 individuals had been diagnosed with measles, of whom 72% lived in the four Williamsburg zip codes that were the focus of the Order and Resolution. Of the 654 individuals, 52 were hospitalized, 34 developed pneumonia, and 19 were admitted to intensive care. After the April 9, 2019 Order, 15,541 doses of the MMR vaccine were administered in Williamsburg and Borough Park, another neighborhood in which measles cases were being diagnosed at that time. The Health Alert contained the following caveat:

Although community transmission associated with this measles outbreak has ended, international importations of measles pose a continued risk of outbreaks in New York City. Further, measles cases continue to occur elsewhere in the United States, including in New York State, posing ongoing risk of reintroduction of measles into NYC neighborhoods where there are pockets of unvaccinated individuals, thus re-igniting community transmission of measles. To achieve high population immunity and prevent future outbreaks, providers must ensure that patients receive their first dose of measles, mumps, and rubella (MMR) vaccine at age 12 months and a second dose at age 4 years....

THE PETITION SHOULD BE DISMISSED

67. The petition should be dismissed for failure to state a cause of action.

68. Since petitioners have admitted that they were in violation as alleged in the summonses they challenge herein, that is, they admit to not having had the MMR vaccination administered to the subject children, the determinations finding them in violation are intrinsically rational and not arbitrary or capricious.

69. Specifically, at the hearings held at OATH, petitioners did not challenge the allegations in the summonses that each of them had failed to comply with a DOHMH order to have the MMR vaccine administered to their child as was set forth in both the Order and the Resolution. Rather, they attempted to undermine the validity of the medical basis underlying the Order and the Resolution, namely, the national medical consensus regarding the safety and efficacy of the MMR vaccine and the danger of deliberately allowing people to contract “wild measles.” In addition, petitioners interposed various purported defenses that were not valid defenses to the charges. Thus, they did not contest the allegations against them in the summonses that they had failed to have the MMR vaccine administered to the subject children.

70. Furthermore, in the instant pleading, petitioners concede that they were in violation as charged in the summonses challenged herein (petition ¶ 6).

71. The Department’s 2019 Order and Resolution mandating the administration of the MMR vaccine in certain Williamsburg zip codes to combat a measles epidemic in that area was rational as a matter of law, as the mandate was in conformance with national medical standards for the combatting of measles.

72. Thus, petitioners’ challenge herein to the safety, efficacy, and lawfulness of the DOHMH requirement in the spring of 2019 that the MMR vaccine be administered as ordered or else be subject to a civil penalty fails to state a cause of action, as it is indisputable that the Department’s public health mandate was rationally based on national medical standards and that petitioners violated the DOHMH order based on those standards.

73. The various constitutional defenses interposed herein by petitioners fail as a matter of law, as petitioners allege that the violations arise from being forced to have their

children vaccinated, and neither the Order nor the Resolution mandated forcible vaccination.

Thus, these defenses are to a non-existent mandate.

CONCLUSION

74. The Department of Health and Mental Hygiene respectfully requests that the instant proceeding be dismissed for failure to state a cause of action.

75. However, in the event that this cross-motion to dismiss is denied, respondent requests forty-five days from its receipt of notice of entry in which to answer the petition.

Dated: Brooklyn, New York
January 4, 2021


LOUISE MOED

Index No. 156722/2020

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein,
Malky Roth-Tabak,

Plaintiffs-Petitioners,

-against-

Department of Health and Mental Hygiene of the City
Of New York,

Defendant-Respondent.

**NOTICE OF CROSS-MOTION TO DISMISS
with SUPPORTING PAPERS**

JAMES E. JOHNSON
*Corporation Counsel of the City of New York
Attorney for Defendant-Respondent
100 Church Street (Admin. Law Div.)
New York, NY 10007
Of Counsel: Louise Moed
Tel: (212) 356-2180
Matter No. 2020-035483*

*Due and timely service is hereby admitted.
New York, NY, 2021 . . .*

..... Esq.

Attorney for.....

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF KINGS

----- X

C.F., on her own behalf and on behalf of her minor children; M.F. on her own behalf and on behalf of her minor children; B.D. on her own behalf and on behalf of her minor children; A. L. on her own behalf and on behalf of her minor child; and M.N.. on her own behalf and on behalf of her minor child,

Petitioners,

-against-

THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and DR. OXIRIS BARBOT, M.D., in her official capacity as Commissioner of the New York City Department of Health and Mental Hygiene,

Respondents,

AS AND FOR A PROCEEDING BROUGHT
PUSUANT TO ARTICLE 78 OF THE CPLR

----- X

AFFIRMATION IN
OPPOSITION TO
PRELIMINARY
INJUNCTION

Index Number: 508356/2019

DEMETRE DASKALAKIS, a physician licensed to practice medicine in the State of New York, affirms, pursuant to CPLR 2106, the following to be true subject to penalties of perjury:

1. I have been employed by the New York City Department of Health and Mental Hygiene of the City of New York (the "Department" or "DOHMH") since 2014 and I have been Deputy Commissioner of the Division of Disease Control (the "Division") since 2017. I hold an M.D. degree awarded by the New York University School of Medicine and a Master of Public Health degree from the Harvard School of Public Health. In addition to being a licensed physician, I am Board Certified in Internal Medicine and Infectious

Diseases. In my capacity as Deputy Commissioner, I am responsible for all of the infectious disease programming at DOHMH. My responsibilities include oversight of several Bureaus within the Department, including the Bureau of Immunization and the Citywide Immunization Registry (“CIR”). Additionally, I have served as the Incident Commander in several infectious disease responses, including the current response to a measles outbreak in Brooklyn. Since joining the Health Department in 2014 as an Assistant Commissioner, I have participated as leadership in urgent and emergent outbreak responses including the public health responses to Ebola, Zika, and multiple outbreaks of Legionnaire’s Diseases in NYC.

2. I make this affirmation in opposition to Petitioners’ application for a preliminary injunction, and to provide background information about the work of the Department in the control of infectious diseases, and particularly the control of measles.

THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

3. Pursuant to section 556 of the Charter of the City of New York, the Department is responsible, among other things, for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health.

4. The activities of the Division include keeping a registry of cases of infectious diseases, including measles, that are reported to us by physicians, hospitals, and laboratories. City and State regulations mandate such reporting of infectious diseases, and the maintenance of such records by the DOHMH. On the basis of the data we collect, we prepare epidemiological reports and other materials.

5. The Division conducts investigations of all reported measles cases including where the infection was acquired, identifying contacts exposed to a measles case when that person was infectious, checking the vaccination status of the contacts and when indicated recommending, if the contact is within 72 hours, or six days, of his or her exposure, rapid vaccination or the administration of immune globulin respectively to prevent infection or prevent the likelihood of severe complications. Exposed persons who are not immune and receive vaccine or immune globulin are told to stay home for the 21 day incubation period. Further, steps are taken to limit exposure and infections in settings such as health care facilities and schools.

6. The Division is also responsible for collection of vaccine records of New York City residents to help ensure that people receive life-saving immunizations, to monitor vaccination rates and to protect public health which are maintained in the Citywide Immunization Registry ("CIR"). The CIR vaccine records are confidential and contain all immunizations reported by NYC health care providers for city residents younger than 19, including immunizations against measles. Providers are required by law to make these reports. Immunizations may also be reported for adults, with their consent. This record is official and may be submitted to child care centers, schools, camps and employers.

7. The Bureau of Immunization in the Division is responsible for compliance with school immunization requirements, case management of pregnant women with chronic hepatitis B infection and their infants, maintenance of the CIR, the Vaccines for Children program (VFC), conducting office visits to practices participating in VFC to ensure proper storage and handling of vaccine and compliance with program requirements, quality assurance activities to achieve high vaccination rates at VFC practices, promotion of adult

vaccination, delivery of immunization services at DOHMH’s immunization clinic, provider and public education about vaccines as well as surveillance of vaccine-preventable diseases like measles. Further, each year the Bureau distributes about \$2.6 million worth of Measles-Mumps-Rubella (MMR) vaccine to approximately 1400 providers citywide who are enrolled in VFC.

BACKGROUND INFORMATION ON MEASLES¹

8. According to the United States Center for Disease Control (“CDC”), measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications.

9. Measles is easily transmitted from a sickened person to others who lack immunity to the disease. Measles is one of the most contagious of all infectious diseases; up to 9 out of 10 non-immune persons (90 percent) who come into contact with a measles patient, or a space where a measles patient recently has been, will develop measles. The virus is transmitted by direct contact with infectious droplets or by airborne spread when an infected person breathes, coughs, or sneezes. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an

¹ Information contained in this section may be found on the publicly available United States Center for Disease Control (CDC) website section on Measles, located at <https://www.cdc.gov/measles/index.html> and on other webpages found through the embedded links to the Measles subsections (last accessed April 16, 2019.)

infectious person recently has been. If other people breathe the contaminated air or touch the infected surface, then touch their eyes, noses, or mouths, they can become infected. A person can spread measles from four days before through four days after the appearance of the rash.

10. Measles can be serious in all age groups. However, children younger than 5 years of age and adults older than 20 years of age are more likely to suffer from measles complications. Common measles complications include ear infections and diarrhea. Some people may suffer from severe complications, such as pneumonia (infection of the lungs) and encephalitis (swelling of the brain). They may need to be hospitalized and could die. As many as one out of every 20 children with measles gets pneumonia, the most common cause of death from measles in young children. About one child out of every 1,000 who get measles will develop encephalitis (swelling of the brain) that can lead to convulsions and can leave the child deaf or with intellectual disability. For every 1,000 children who get measles, one or two will die from it. Measles may cause a pregnant woman to give birth prematurely, or have a low-birth-weight baby.

11. Measles can also result in long-term complications. Subacute sclerosing panencephalitis (SSPE) is a rare, but fatal disease of the central nervous system, characterized by behavioral and intellectual deterioration and seizures, that results from a measles virus infection acquired earlier in life. SSPE generally develops 7 to 10 years after a person has measles, even though the person seems to have fully recovered from the illness. Since measles was eliminated in 2000, SSPE is rarely reported in the United States. The CDC reports that among people who contracted measles during the resurgence in the United States in 1989 to 1991, 4 to 11 out of every 100,000 were estimated to be at risk for

developing SSPE. The risk of developing SSPE may be higher for a person who gets measles before they are two years of age.

MEASLES PREVENTION

12. Measles is so contagious that each new case of it that occurs severely hinders the ability of health officials to curb an outbreak, especially in under-vaccinated communities with higher rates of unvaccinated, non-immune individuals.

13. Although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. Measles remains one of the leading causes of death worldwide, according to the World Health Organization, an estimated 110,000 deaths in occurred in 2017, mostly among children under the age of five. Measles transmission was declared eliminated in the United States in 2000, though there have been limited outbreaks reported since then.

14. The CDC recommends that children get two doses of MMR vaccine, with the first dose at 12 through 15 months of age, and the second dose at 4 through 6 years of age.

15. Before the measles vaccination program started in 1963, an estimated 3 to 4 million people got measles each year in the United States. Of these, approximately 500,000 cases were reported each year to CDC; of these, 400 to 500 cases resulted in death, 48,000 cases required hospitalization, and 1,000 infected people developed encephalitis (brain swelling) from measles. Since then, widespread use of measles vaccine has led to a greater than 99% reduction in measles cases compared with the pre-vaccine era. However, recently there has been an increase in outbreaks, which the CDC defines as three or more cases. The CDC reports that the U.S. experienced 17 outbreaks in 2018. These outbreaks

have occurred in under-vaccinated communities when a member of that community has returned from travel infected with the disease. Three outbreaks in New York State, New York City, and New Jersey, respectively, contributed to most of the cases. Cases in all three states occurred primarily among unvaccinated people in Orthodox Jewish communities. The CDC reports that from January 1 to April 11, 2019, a preliminary count of 555 individual cases of measles have been confirmed in 20 states. This is the second-greatest number of cases reported in the U.S. since measles was eliminated in 2000.

16. According to the CDC, prompt recognition, reporting, and investigation of measles is important because the spread of the disease can be limited with early case identification and public health response including vaccination.

17. Persons who received MMR do not infect other people and are not responsible for measles transmission. Person-to-person transmission of the vaccine virus has never been documented.

18. I am aware that the reasons some parents cite for not vaccinating their children include concerns about the safety of the MMR vaccine and that the vaccine causes autism. The current MMR vaccine used in the United States was licensed in 1971 and has a long and strong safety record. The article that first suggested a relationship between measles vaccine and brain damage was based on a now discredited article published in 1998. Those finding could never be reproduced, and the article was retracted in 2010. The lead author of that article can no longer practice medicine in the United Kingdom. Since 1999, there have been over 25 articles published in the scientific literature that demonstrate the lack of such an association including reviews by the Institute of Medicine (source: <http://immunize.org/talking-about-vaccines/mmr.asp>).

19. Some parents also say that it is safer and better to get the ‘natural’ wild-type measles infection but this could not be further from the truth. This is best demonstrated by the reduction in measles cases and measles deaths (cited above) in the US and worldwide (80% reduction in deaths from 2000 to 2017, preventing an estimated 21.1 million measles deaths, source <https://www.who.int/en/news-room/fact-sheets/detail/measles>) after the introduction of an effective measles vaccine. While in some cases a person will develop a rash and/or fever following receipt of the MMR vaccine, the fever and rash are both less serious than with natural measles and non-transmissible, meaning other people cannot contract this measles by coming in contact a vaccinated person. During this outbreak investigation, 17 persons have been reported to the Health Department who developed these symptoms after vaccination and were found to have vaccine-related virus. These cases are not included in the count of confirmed measles cases reported during the outbreak because the vaccine-related strain is not transmissible and does not cause the severe illness characterized by wild-type infection.. It should be noted that if a person is exposed to measles and is vaccinated afterwards, in particular after the 72 hour window, they may still develop wild-type measles that is unrelated to having been vaccinated.

EFFORTS OF DEPARTMENT TO CONTROL THE MEASLES OUTBREAK IN NYC

20. There is currently an active measles outbreak within neighborhoods in ZIP codes 11205, 11206, 11211 and 11249 (“Williamsburg”) and ZIP codes 11204, 11218, 11219, 11230 (“Borough Park”) in Brooklyn that qualifies as a public health threat. The outbreak began in early October 2018 and, as of April 15, 2019, has resulted in over 300 cases of this vaccine-preventable disease. In the last three months, the vast majority of these cases have been in Williamsburg residents in ZIP codes 11205, 11206, 11211 and 11249.

21. As of April 15, there have been a total of 329 reported measles cases in the current outbreak in NYC: 267 in Williamsburg; 52 in Borough Park; 25 individuals have been hospitalized, of which 6 were in Intensive Care. 52 chains of transmission, discrete outbreaks that comprise the bigger outbreak of measles in Brooklyn, have been identified, including 32 that are still in the window of active transmission.

22. The Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the healthcare providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in various locations.

23. DOHMH has engaged in the following community outreach initiatives:

- DOHMH personnel, officials from city agencies, and elected officials have held meetings with community leaders to provide information and discuss means of outreach to the community.
- Robo-calls from DOHMH were made to 30,000 households, with additional calls are planned.
- DOHMH has sent six rounds of letters to the principals of yeshivas and to parents of students at schools within the affected zip codes.
- DOHMH has placed three rounds of ads in eighteen newspapers since November.
- DOHMH has made widespread distribution of measles informational booklets to nearly 30,000 community households, and has distributed approximately 13,000 informational booklets through DOHMH community partners.
- DOHMH has been in communication with all elected officials in the affected communities, including provision of weekly updates for measles case counts.

24. DOHMH has engaged in the following outreach initiatives with healthcare providers:

- DOHMH distributed an additional 18,000 doses of the MMR vaccine to community healthcare providers serving the affected community early in the outbreak, which was twice as many as the same time last year. There is a good supply of MMR vaccine and DOHMH has continued to supply MMR vaccine to healthcare providers through the current distribution system.
- DOHMH staff were embedded in medical centers in the affected community to ensure compliance with infection control.
- DOHMH issued three Health Alerts citywide, each distributed to nearly 13,000 providers which were in addition to several communications with health care providers serving the affected community.
- DOHMH advised providers to add an extra dose of MMR between 6-11 months old, in order to protect more children.
- DOHMH conducted training for the Jewish Orthodox Nurses organization and medical providers serving the affected community, and have had multiple meetings with key community health care coalitions/committees.
- DOHMH distributed informational posters and booklets about measles to community-based clinics.
- DOHMH has regularly consulted with the New York State Department of Health and the CDC, as well as with other jurisdictions experiencing outbreaks.

25. These DOHMH efforts have resulted in more than 8,700 additional MMR vaccinations in Williamsburg and Borough Park between October 1, 2018 and April 14, 2019 compared to the same time period last year.

26. On November 7, 2018, a letter was sent to the principals/directors of yeshivas and child care facilities in Williamsburg informing them about the measles outbreak.

27. Starting in December, the City mandated that over 300 yeshiva schools and childcare centers in the outbreak zip codes must exclude unvaccinated, under-vaccinated and/or non-immune children – even those children with religious or medical exemptions.

- On December 6, 2018, letters were sent to principals/directors of yeshivas and child care facilities in certain zip codes, within the neighborhoods where the outbreak is occurring informing them that, effective December 7, 2018, every student who is not vaccinated with the required number of doses of measles-mumps-rubella (MMR) vaccine will not be permitted to attend school, regardless of whether a case of measles has occurred in the school. The letter stated that principals or directors are responsible for enforcing exclusion of students and compliance with all school-required immunizations and that to ensure compliance, every yeshiva is subject to audit by the Department of Health, and noncompliance can result in Commissioners Orders and fines.
- On December 21, 2018, letters were sent to yeshiva and child care principals/directors stating that as recognized by the State Education Department and pursuant to New York State Department of Health Regulation §66-1.10, the New York City Department of Health and Mental Hygiene has the authority to order school heads to exclude children without the required number of doses, including those who have been granted religious or medical exemptions, when there is an outbreak of specific diseases including measles. The authority to exclude includes schools in the affected neighborhoods even where there are no cases of measles in those particular schools.
- On February 13, 2019, letters were sent to yeshiva and child care principals/directors stating that students attending day care programs or yeshivas in zip codes 11230 and 11220 and students in grades kindergarten through grade 12 attending yeshivas in zip codes 11204, 11218 and 11249 may return to school if they are in compliance with routine school immunization requirements. The letters stated that for children attending day care programs, including nursery, Head Start, and pre-kindergarten serving the Orthodox Jewish community in zip codes 11204, 11218 and 11249 and for children attending day care programs and yeshivas in zip codes 11205, 11206, 11211 and 11219, the current exclusions continue to apply; students without the required number of doses of MMR cannot return to school until they are appropriately vaccinated, or until the outbreak is declared over, even if they have an approved religious or medical exemption to measles immunization.
- DOHMH has conducted 255 audits of the affected schools and child care facilities. DOHMH has issued 113 Commissioner Orders, as well as 16 Notices of Violation to 9 sites for failure to comply with DOHMH audits and/or directives to exclude children without the recommended doses of

MMR.

28. However, currently the measles outbreak persists in ZIP codes 11205, 11206, 11211 and 11249 despite these efforts taken by the Department of Health and Mental Hygiene to stop it, because a high rate of people living within Williamsburg have not been vaccinated against measles despite the efforts enumerated above.

CURRENT STATUS OF MEASLES IN WILLIAMSBURG, BROOKLYN

29. The following charts provide information about measles in New York City, which is current as of 4/15/19:

30. CONFIRMED NEW CASES IN PAST WEEK

	Confirmed Cases	New Cases in Past Week
Bensonhurst	1	None
Borough Park	52	3
Brighton Beach	1 (travel-related)	None
Crown Heights	1	None
Midwood/Marine Park	4	1
Williamsburg	267	39
Flushing	2	None
Far Rockaway	1	1
Total	329	44

CASES BY AGE

Age Range	Confirmed Cases
Under 1 year	56
1 – 4 years	162
5 – 18 years	66
Over 18 years	45

CASES BY DATE

Month	New Cases
April 2019	62
March 2019	114
February 2019	63
January 2019	34
December 2018	14
November 2018	28
October 2018	13
September 2018	1

31. In summary, the incidence of measles continues to spread within New York City, and in particular in Williamsburg, Brooklyn.

32. Consequently there remains an on-going threat to public health.

ORDER OF THE COMMISSIONER

33. Pursuant to section 3.01 of the New York City Health Code, Oxiris Barbot, M.D., as the DOHMH Commissioner of Health (“Commissioner”) has authority to declare a public health emergency when there is an urgent threat to the health of New York City residents, and to take such actions that the Commissioner deems necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat.

34. On April 9, 2019, Commissioner Barbot declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn.

35. Commissioner Barbot declared the emergency at a press conference she attended with Mayor De Blasio in Williamsburg. She announced that she was ordering

residents of ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles or face a \$1000 fine² because of the continuing outbreak in the affected zip codes. Early versions of the written order mistakenly identified other zip codes as being covered by the declaration. These typographical errors were corrected later in the day to align with the Commissioner's announcement of where the outbreak persists.

36. The current measles outbreak began in early October 2018 and has resulted in over 300 cases of this vaccine-preventable disease. As previously noted, in the last three months, the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. Yet, the outbreak continues due to low vaccination rates in these four ZIP codes.

37. The Commissioner determined the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York.

38. The Commissioner determined that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contraindicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak.

39. Pursuant to New York City Health Code §3.07, no person "shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any

² <https://www1.nyc.gov/office-of-the-mayor/news/186-19/de-blasio-administration-s-health-department-declares-public-health-emergency-due-measles-crisis#/0>

individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

40. As a result, on April 9, 2019 the Commissioner issued an Order directed to “[A]ll persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York” (the “Order”) (copy annexed as Exhibit “A”), which ordered the following:

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

41. The Order warns that failing to comply with it is a violation of §3.05 of the New York City Health Code. While such a violation is potentially criminal, the Department is enforcing violations of this order civilly. Violators are going to be issued a Notice of Violation (NOV) returnable in the Office of Administrative Trials and Hearings (OATH) where a fine of \$1000 may be upheld against them.

42. The Order lasts until the Board of Health meets tomorrow on April 17, 2019 at which time the Board will determine whether the vaccination requirement should be continued or rescinded.

43. Vaccinations are the most effective way to stop this outbreak. Isolating persons with measles would not work because people with measles are infectious before their rashes appear and it is known that they have the disease. Many of the people who have contracted measles during this outbreak were infected because they came into contact with infected person during his or her prodromal period. Quarantining contacts – anyone who might have come into contact with an infectious person – would be both logistically impossible and a much greater infringement of people’s liberty than simply fining people who chose not to be vaccinated during an outbreak.

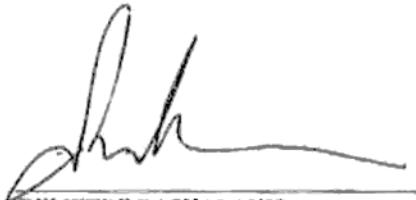
44. Finally, I have reviewed the affidavits submitted by Drs. Richard Moskowitz, Tina Kimmel, Jane Orient, Hendricks Fitzpatrick and Shira Miller. They make many false statements about both measles and the safety of the MMR vaccine. These false statements include suggesting that people who are vaccinated can transmit measles, that measles is virtually always benign and never serious unless occurring with malnutrition, and that the MMR vaccine is linked to autoimmune disorders. These opinions are not supported in the generally accepted medical literature, but come from “experts” on the fringes of the medical community. Dr. Orient, for instance, is the Executive Director of the American Association of Physicians and Surgeons. She is noted for opposing health care of any kind and it publishes a journal with extreme articles like one questioning whether the HIV virus causes AIDS.³ Dr. Moskowitz, who practices homeopathic medicine, has acknowledged

³ See <https://aapsonline.org> and <http://www.jpands.org/jpands1503.htm>

that he "hasn't given any vaccines in over 45 years" and has had "very few things ... published in the mainstream media or scientific journals."⁴

45. Accordingly, the Commissioner's Order to vaccinate was properly issued in order to abate the resurgence of this highly preventable disease and protect the public health and should be upheld.

Dated: New York, New York
April 16, 2019


DEMETRE DASKALAKIS

⁴ See <https://www.ageofautism.com/2017/10/an-interview-with-richard-moskowitz-md-author-of-vaccines-a-reappraisal.html>

EXHIBIT A



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, M.D.
Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, M.D.
Commissioner

ORDER OF THE COMMISSIONER

TO: All persons who reside, work or attend school in the neighborhood of Williamsburg, Brooklyn, New York and to the parents and/or guardians of any child who resides, works or attends school in the neighborhood of Williamsburg, Brooklyn, New York

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249. Since September 2018, more than 250 cases of measles have been documented among people living in Williamsburg and that number continues to grow as new cases are still occurring; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication and in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is an effective and safe vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was largely eliminated in the United States; and

WHEREAS, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs, because a high rate of people living within Williamsburg have not been vaccinated against measles; and

WHEREAS, pursuant to section 556 of the Charter of the City of New York, the Department is responsible for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health; and

WHEREAS, pursuant to section 3.01 of the New York City Health Code, I am authorized to declare a public health emergency and issue orders and take actions that I deem

necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat; and

WHEREAS, I find the ongoing measles outbreak in Williamsburg to be an existing threat to public health in the City of New York; and

WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142; and

WHEREAS, pursuant to New York City Health Code §3.07, no person “shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual... or ...shall fail to do any reasonable act or take any necessary precaution to protect human life and health.”

IT IS HEREBY ORDERED that any person who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this Order being signed by me shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within the 11205, 11206, 11211 and/or 11249 zip codes and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

THIS ORDER shall remain in effect until the next meeting of the New York City Board of Health scheduled for April 17, 2019 at which time it may be continued or rescinded by the Board.



Dated: April 9, 2019

Oxiris Barbot, M.D.
Commissioner of Health

WARNING

Failure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment.

Anyone wishing to object to the order, please write or fax Thomas G. Merrill, General Counsel, New York City Department of Health and Mental Hygiene, 42-09 28th Street (WS 14-38) Long Island City NY 11101-4132; tmerrill@health.nyc.gov telephone: 347-396-6116; fax: 347-396-6087, providing a statement of the reasons for your objection to the order. If you have any questions about how to comply with this Order, please telephone Jane R. Zucker, M.D., M.Sc., Assistant Commissioner, Bureau of Immunization at 347-396-2471.

The following resolution was adopted by the Board of Health on April 17, 2019 and will be published in accordance with §17-148 of the Administrative Code of the City of New York.

Resolution of the Board of Health of the
Department of Health and Mental Hygiene
of the City of New York

At a meeting of the Board of Health of the Department of Health and Mental Hygiene held on April 17, 2019, the following resolution was adopted:

WHEREAS, there is an active outbreak of measles among people residing in the neighborhood of Williamsburg in Brooklyn, New York who live within zip codes 11205, 11206, 11211 and 11249 (the “affected zip codes”); and

WHEREAS, on April 9, 2019 the Commissioner of the Department of Health and Mental Hygiene determined that an urgent public health action was necessary to protect the public from the measles outbreak occurring in the neighborhood of Williamsburg and declared a public health emergency; and

WHEREAS, pursuant to her authority under Health Code §3.01, the Commissioner ordered that anyone who lives, works or resides in the affected zip codes and any child older than six months of age living, residing, or working in any of the affected zip codes be immunized against measles; and

WHEREAS, the Order subjects a person to a civil fine , unless such person or, for a child, such person’s parent or guardian, can demonstrate that such person has immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and

WHEREAS, pursuant to Health Code §3.01, the Order issued by the Commissioner is only in effect until the Board of Health convenes and either continues or rescinds the Commissioner’s exercise of authority; and

WHEREAS, the Board of Health has taken and filed among its records and reports that since September 2018 more than 300 cases of measles have been documented in the City of New York with the vast majority occurring among people residing in the affected zip codes and that new cases of measles are still occurring at an alarming rate; and

WHEREAS, measles is a highly contagious viral disease that can result in serious health complications such as pneumonia, encephalitis (swelling of the brain) and death. About a third of reported measles cases have at least one complication. Measles can be serious in all age groups. However, infants, young children, pregnant persons, people whose immune systems are weak and adults are more likely to suffer from measles complications; and

WHEREAS, measles is easily transmitted from a sickened person to others who lack immunity to the disease. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person recently has been; and

WHEREAS, although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a proven safe and effective vaccine that will prevent its transmission. While measles remains one of the leading causes of death among young children in parts of the world where the vaccination is not available, the disease until this outbreak was eliminated in the United States; and

WHEREAS, because a high rate of people living within the affected zip codes in Williamsburg have not been vaccinated against measles, the measles outbreak persists in Williamsburg despite other efforts taken by the Department of Health and Mental Hygiene to stop it, including orders excluding unvaccinated children from attending preschools and daycare programs; and

WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance; and

WHEREAS, the outbreak is occurring because a large number of people residing in the affected zip codes have not been vaccinated against measles; and

WHEREAS, the only way to end the outbreak is to require that people residing, working or attending school in any of the affected zip codes be vaccinated against or otherwise have immunity against measles; and

WHEREAS, personal service or service pursuant to subdivisions (a) or (b) of §17-148 of the Administrative Code of the City of New York of orders requiring the abatement of such nuisances and conditions in effect dangerous to life and health upon each of the persons who, pursuant to the provisions of Title 17 of the Administrative Code of the City of New York, has a duty or liability to abate such nuisances and conditions, would result in a delay prejudicial to the public health, welfare, and safety; now, therefore, be it

RESOLVED, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg and that the outbreak poses a public nuisance because it is immediately dangerous to life and health; and be it further

RESOLVED, that the Board of Health hereby declares that any person who lives or works within the affected zip codes shall be vaccinated against measles unless such person can demonstrate immunity to the disease or document to the satisfaction of the Department that such person should be medically exempt from this requirement; and be it further

RESOLVED, that the parent or guardian of any child six months of age or older who lives or attends school, preschool or child care within the affected zip codes and who has not received the MMR vaccine shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document to the satisfaction of the Department that such child should be medically exempt from this requirement; and be it further

RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene.

RESOLVED further, that this resolution shall take effect immediately and publication shall be in accordance with New York City Administrative Code §17-148.

(As adopted by the Board of Health on April 17, 2019)



Frequently Asked Questions: NYC Measles Vaccine Order for ZIP codes 11205, 11206, 11211 and 11249

On April 9, the Health Department declared a public health emergency and issued a measles vaccine order in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249 in Brooklyn. This FAQ provides additional information on this announcement as well as the associated measles vaccine order.

Why did the Health Department declare a public health emergency in response to the measles outbreak in ZIP codes 11205, 11206, 11211 and 11249?

The Commissioner of Health can declare a public health emergency when there is an urgent threat to the health of New Yorkers.

There is currently an active measles outbreak in the Williamsburg and Borough Park neighborhoods of Brooklyn that qualifies as such a threat. The outbreak began in early October 2018 and has resulted in nearly 300 cases of this vaccine-preventable disease. In the last three months the vast majority of these cases have been in residents of ZIP codes 11205, 11206, 11211 and 11249. The Health Department has tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the medical providers who serve them. Additionally, the Health Department required any unvaccinated children to be excluded from yeshivas and child care programs serving this community. However, the outbreak continues due to low vaccination rates in these ZIP codes.

This outbreak is being fueled by the spread of dangerous misinformation on the safety and effectiveness of the MMR vaccine. The Health Department stands with the majority of people in this community who have worked hard to protect their children and others at risk. There is an urgent need to end this outbreak and protect New Yorkers from this potentially fatal infection. This declaration will help improve vaccination rates in the affected communities.

What does the measles vaccine order do?

To stop the spread of measles in New York City, the Health Department requires that adults and children ages 6 months and older who live, work or go to school in ZIP codes 11205, 11206, 11211 and 11249 receive a measles, mumps and rubella (MMR) vaccine. People who cannot receive the vaccine for valid medical reasons, including pregnant individuals, are exempt from the vaccine order.

The risk of getting the measles is low for vaccinated or immune individuals. For most people in ZIP codes 11205, 11206, 11211 and 11249, this order should encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

Are infants 6 through 11 months included in the vaccine order?

Yes, all infants living or attending child care in ZIP codes 11205, 11206, 11211 and 11249 are included in the vaccine order. The early dose of the MMR vaccine will protect them during the current outbreak. Children should then return to the recommended vaccine schedule and the first dose of the MMR vaccine should be repeated at 12 months of age. Children must have two doses of the MMR vaccine to attend school (kindergarten – 12th grade).

Please use the following guidance regarding an early dose of the MMR vaccine for infants 6 through 11 months of age who do not live in ZIP codes 11205, 11206, 11211 and 11249:

- Recommended for members of communities with a known measles outbreak in Borough Park and Crown Heights.
- Suggested for members of the Orthodox Jewish community in New York City.
- Recommended for all infants traveling internationally or to a community with a known measles outbreak.

What if I work in ZIP codes 11205, 11206, 11211 and 11249?

If you work for a business located in ZIP codes 11205, 11206, 11211 and 11249 then you are required to have the MMR vaccine to stop the spread of measles. We encourage you to check your immunization records or talk to your health care provider to confirm your vaccination history or immunity status.

How will the Health Department know who isn't vaccinated?

When Health Department staff identify a patient with measles, they also identify anyone that person has had contact with. The Health Department and health care providers connect these contacts with immunization or other preventive measures and work with them to reduce the risk of measles. Health Department staff also use the Citywide Immunization Registry (CIR) to check the vaccine record of any individual who may have been in contact with a patient with measles. If immunization records are not available, the Health Department may request other evidence of immunity to measles. For example, a blood test, called a measles serology, can prove that someone is immune to measles through prior vaccination or infection with the measles virus. Your health care provider can order this common test and arrange to have your blood drawn. Anyone in ZIP codes 11205, 11206, 11211 and 11249 who cannot prove they are immune to measles by producing immunization records or demonstrate immunity with a positive measles serology blood test will be considered non-immune and unvaccinated by the Health Department and will be in violation of the vaccine order.

What happens if I refuse the vaccine?

The Health Department has ordered everyone in ZIP codes 11205, 11206, 11211 and 11249 to get vaccinated if they have not already done so. The Health Department may issue a civil summons to anyone who lives, works or attends school in the affected ZIP codes and has not been vaccinated as of April 11, 2019, and does not provide proof of immunity or a valid medical exemption to the Health Department. If the unvaccinated person is a child, the summons will be issued to the parent. The person

receiving the summons will be entitled to a hearing at the New York City Office of Administrative Trials and Hearings. If the hearing officer upholds the summons, a \$1,000 penalty will be imposed. Failing to appear at the hearing or respond to the summons will result in a \$2,000 fine.

What happens if I cannot take the vaccine because of a medical condition or other medical reason?

There are few medical reasons that would prevent you from receiving the MMR vaccine. If you are a known contact of a measles case and there is a medical reason that would prevent you from receiving the MMR vaccine, including pregnancy, you will be asked to produce specific documentation from a healthcare provider licensed to practice in New York. This medical documentation must explicitly state the condition that makes it impossible for you or your child to be vaccinated. A general provider note without a clear statement of why you cannot receive the vaccine will not be accepted as a valid medical exemption. If your documentation is confirmed, the fine against you will be withdrawn.

Individuals with medical reasons that prevent them from receiving the MMR vaccine after exposure to measles may be able to receive another preventive treatment called immune globulin. The Health Department will provide guidance to eligible individuals who require immune globulin.

What else is the Health Department doing to stop the spread of measles?

The Health Department will continue to require yeshivas and child care programs that serve the affected community and are located in ZIP codes 11205, 11206, 11211 and 11249 to exclude children who do not have the required doses of the MMR vaccine. Children will be allowed to go back to their child care or yeshiva if they prove they are up to date on their MMR vaccines or have laboratory tests (measles serology) that show they are immune to measles. These exclusion requirements are in place until the end of the outbreak or until the Health Department determines it is safe for unvaccinated students to attend these yeshivas or child care facilities. The Health Department is also partnering with community-based medical providers, organizations, religious leaders and other locally trusted voices to share education on vaccinations and engage with concerned families.

Which schools are affected by the exclusion requirements?

Yeshivas and child care programs in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg have been given a Commissioner's Order to exclude unvaccinated children from attending school during the outbreak. Additional yeshivas and child care programs in ZIP codes 11204, 11218 and 11219 in Borough Park have also been notified and are required to exclude unvaccinated children. These schools are the only schools required to meet the outbreak exclusion requirements at this time. Students who attend child care or yeshivas in these ZIP codes must be excluded from attending school even if they have a religious or medical exemption or a medical note. Child care programs must also exclude staff who are not vaccinated and do not have proof of immunity. All unvaccinated or non-immune students in any child care or school, in any ZIP code, with a known measles case will also be excluded from school as determined by the Health Department.

Outbreak-Related School Attendance Exclusions

Unvaccinated child lives in or attends a child care program or school located in the following ZIP code	Unvaccinated child is in nursery, Head Start or pre-K program	Unvaccinated child is in grade kindergarten through 12	Unvaccinated child is in grade 9-12 and school has grades 9-12 only
11204	Cannot attend	Can attend	Can attend
11205	Cannot attend	Cannot attend	Cannot attend
11206	Cannot attend	Cannot attend	Cannot attend
11211	Cannot attend	Cannot attend	Cannot attend
11218	Cannot attend	Can attend	Can attend
11219	Cannot attend	Cannot attend	Can attend
11249	Cannot attend	Cannot attend	Cannot attend

Do the outbreak-related school exclusion requirements apply to public or private schools that do not serve the Orthodox Jewish community?

No, these exclusion requirements are currently only in effect for yeshivas or child care programs serving the Orthodox Jewish community in ZIP codes 11205, 11206, 11211 and 11249 in Williamsburg, and in ZIP codes 11204, 11218 and 11219 in Borough Park. To date there have been no cases or transmissions associated with children in these other types of programs or schools, so there is no reason to extend outbreak-related exclusions to public or private programs at this time. The Health Department will adjust these outbreak-related exclusions in the future if outbreak patterns change. For now, it is critical that all children in public or private schools follow the standard Department of Education immunization requirements as well as the current MMR vaccine order requirements to prevent additional measles cases. For more information on Department of Education immunization requirements, visit schools.nyc.gov.

What is measles?

Measles is a viral infection that causes fever and a rash. Almost 30% of people with measles will have complications from this infection, including pneumonia, brain swelling, diarrhea, ear infection, hospitalization and potentially death. It is highly contagious and anyone who is not vaccinated against the virus can get it at any age. Measles can be very severe in people with weakened immune systems and pregnant individuals.

How is measles spread?

Measles is spread through the air when an infected person sneezes or coughs, or even when they breathe. A person with measles is contagious four days before the rash appears and continues to be contagious for four days after the rash appears.

Measles is a highly contagious virus that remains active and capable of causing infection in the air and on surfaces for up to two hours.

How can measles be prevented?

Vaccination is the best way to prevent measles. Anyone who has received two doses of a measles-containing vaccine or was born before 1957 (likely immune because of natural infection) is considered immune and highly unlikely to get measles.

All children starting at 12 months old enrolled in pre-kindergarten, nursery school, child care programs and Head Start are required to receive one dose of the MMR vaccine.

Children must have two doses of the MMR vaccine to attend school (kindergarten through 12th grade).

Where can I get the MMR vaccine?

To get the MMR vaccine, check with your health care provider. You can also call 311 or visit nyc.gov/health/clinics.

Where can I get more information about measles?

Talk to your health care provider, call 311 or visit these online resources for more information:

- Measles: nyc.gov/health and search for “measles”
- Measles (Immunization Action Coalition): vaccineinformation.org/measles
- Measles Overview (Centers for Disease Control): cdc.gov/measles

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,

Petitioner,

Summons No.
30198-19L0

- against -

MALKY TABAK,

Respondent.

August 28, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORAIN PEONE, ESQ.
PETITIONER'S REPRESENTATIVES
Department Of Health & Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>
Dr. Rosen		86			

<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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1 H.O. DAVID LEUNG: Okay, we are on the
2 record and recording has begun. My name is David
3 Leung, Hearing Officer. It's August 28, 2019, 10:11
4 in the morning. We are here today on a Health
5 Department issued summons number 30198-19L0, or is
6 that L0? It looks like L0, issued to Malky Tabak at
7 585 Marcy Avenue, Apartment 2E. We have attorneys
8 and representatives from the Department of Health.
9 Can you put your name on the record and spell it,
10 please?

11 MR. THOMAS MERRILL: For the Department of
12 Health, Thomas Merrill, M-E-R-R-I-L-L.

13 H.O. LEUNG: Okay. And who else is here
14 from the Department of Health?

15 MS. LORAIN PEONE: Loraine Peone, L-O-R-A-
16 I-N-E P-E-O-N-E, attorney for the Department of
17 Health.

18 H.O. LEUNG: Okay. Mr. Mer-, Merrill, what
19 is your position with DOH?

20 MR. MERRILL: I'm the General Counsel.

21 H.O. LEUNG: General Counsel. And who else
22 is here from the Department of Health?

23 DR. JENNIFER ROSEN: Jennifer Rosen, R-O-S-
24 E-N.

25 H.O. LEUNG: Okay. And what is your title

1 at DOH?

2 DR. ROSEN: Physician with the Department
3 of Health.

4 H.O. LEUNG: Physician? Okay.

5 MR. JOSEPH RUSSO: I am Joseph Russo
6 [phonetic], R-U-S-S-O, paralegal observing.

7 H.O. LEUNG: Okay. And for the respondent?

8 MR. AARON SIRI: Good morning, Your Honor.
9 Aaron Siri, A-A-R-O-N S-I-R-I.

10 H.O. LEUNG: Okay.

11 MR. SIRI: Is it okay --

12 H.O. LEUNG: Go ahead.

13 MR. SIRI: Is it okay if we take up some of
14 your real estate?

15 H.O. LEUNG: Absolutely. Whatever you need
16 --

17 MR. SIRI: Okay. Just want to make sure.

18 H.O. LEUNG: No, no.

19 MR. SIRI: Thank you.

20 H.O. LEUNG: You can use whatever space you
21 need. Dr. Rosen, do you swear or affirm the
22 testimony you give will be the truth?

23 DR. ROSEN: I do.

24 [WHEREUPON THE WITNESS, J E N N I F E R R
25 O S E N, WAS DULY SWORN.]

1 H.O. LEUNG: Thank you. Mr. Siri, I have
2 to -- I'm going to go over these rights and for all
3 the hearings that follow, if you -- just to save, I'm
4 going to ask you. You have a right to have an
5 interpreter, you don't need one, is that correct?

6 MR. SIRI: That's right.

7 H.O. LEUNG: And do you waive the need to
8 have the actual officer or inspector that wrote the
9 ticket appear at the hearing? You have a right to
10 have that inspector present to cross examine him or
11 her.

12 MR. SIRI: No, I don't, Your Honor.

13 H.O. LEUNG: So, you are okay to proceed
14 without the inspector?

15 MR. SIRI: No, I don't waive the right.

16 H.O. LEUNG: You don't waive, okay. So,
17 are you demanding the presence of the issuing
18 officer?

19 MR. SIRI: Yes.

20 H.O. LEUNG: Okay. Who is the issuing
21 officer on this summons, the inspector?

22 MR. MERRILL: It is Delbert Kathleen
23 [phonetic].

24 H.O. LEUNG: Okay. Counsel, I'm going to
25 ask you to put on the record your basis for

1 requesting the issuing officer.

2 MR. SIRI: Sure. In the summons, Your
3 Honor, it says the issuing officer is the one that
4 swears to the accuracy of the violation.

5 H.O. LEUNG: Right.

6 MR. SIRI: The violation claims under
7 penalty of perjury that respondent has failed to
8 vaccinate child CR and otherwise submit acceptable
9 proof of immunity in violation of the order. I
10 believe that the issuing officer should be able to --
11 should be here to explain how they arrived at the
12 definitive conclusion that the respondent didn't
13 submit acceptable proof of immunity. Was the
14 respondent requested to submit the proof of immunity?

15 H.O. LEUNG: Okay. Let me just --

16 MR. SIRI: Yeah.

17 H.O. LEUNG: Let me just -- what happens is
18 you have a under OATH rules, hearing rules. You have
19 a right to ask that the hearing officer appear. I
20 have to make a determination --

21 MR. SIRI: I understand.

22 H.O. LEUNG: -- as to whether or not the
23 issuing officer's appearance is necessary for you as
24 the respondent to get a fair hearing. So, I'm going
25 to turn to the petitioner. Counsel for respondent

1 has made an application to request that the issuing
2 officer appear on the basis of, and if I summarize it
3 incorrectly, let me know, that the sworn allegations
4 are made out by the issuing officer and that you
5 believe that you should have an opportunity to cross
6 examine him or her --

7 MR. MERRILL: Her, her.

8 H.O. LEUNG: -- as to the basis --

9 MR. MERRILL: Her.

10 H.O. LEUNG: I'm sorry, her as to the basis
11 of how she, she made the allegations as written in
12 the summons, is that correct?

13 MR. SIRI: Yes, including that it was, you
14 know, including regarding the medical appropriateness
15 to provide this injection as well as, as I said, the,
16 the alleged violation.

17 H.O. LEUNG: Okay.

18 MR. SIRI: Yeah, I'll leave it at that.

19 H.O. LEUNG: Okay. I'm going to turn --

20 MR. SIRI: I can get into more specifics,
21 if you want.

22 H.O. LEUNG: Great. I'm going to turn to
23 DOH and ask you to respond as to whether or not --

24 MR. MERRILL: Yeah. Sure, Your Honor. I -
25 - so, I don't believe, I think that anything that the

1 petitioner wants -- or respondent wants, Dr. Rosen is
2 here, can explain. The, the allegations were -- the
3 NOVs were issued based on the -- there was an order
4 that everybody be immunized. So, the allegations
5 were issued -- excuse me, the NOV was issued after
6 they checked with immunization registry for people
7 with vaccinations was done and I think Dr. Rosen can
8 testify about that as well. Dr. Rosen can also
9 testify about, you know, efforts in terms of reaching
10 out to contacts and in terms of explaining the
11 medical necessity of vaccine, she is more than
12 capable of doing that.

13 H.O. LEUNG: Okay. Mr. Siri, how do you
14 respond to their --

15 MR. SIRI: Well, it's about the medical
16 appropriateness for this particular respondent.

17 H.O. LEUNG: Okay.

18 MR. SIRI: Not vaccines in general, right?

19 H.O. LEUNG: Okay.

20 MR. SIRI: Like every drug --

21 H.O. LEUNG: Right.

22 MR. SIRI: -- not everybody -- you're going
23 to bring a penicillin.

24 H.O. LEUNG: And do you --

25 MR. SIRI: And so one --

1 H.O. LEUNG: -- do you have testimony to
2 rebut what she has put down in the, in the -- you're
3 saying that you want to put the inspector to the
4 burden of proving how she alleged what she alleged?

5 MR. SIRI: Right. I mean, she is -- she --
6 you know, under this violation, she says that my
7 client did not submit acceptable proof of immunity
8 was -- I, I believe that the, you know, the issuing
9 officer who swore to that should be able to
10 substantiate, for example, was that ever requested
11 and how did she determine that there was no
12 acceptable proof of immunity. And also that the,
13 again and most importantly, I think is that it was
14 medically appropriate for this child to be immunized.

15 H.O. LEUNG: Okay, I'm going to turn to
16 Department of Health. Was this an allegation of
17 failure to comply? Is this a -- the --

18 MR. MERRILL: This is a failure to be
19 immunized, Your Honor.

20 H.O. LEUNG: Failure to immunize, okay.

21 MR. MERRILL: In violation of the order to
22 be immunized that, that was issued for residents of
23 Williamsburg.

24 H.O. LEUNG: Great. So, a failure to
25 comply with the Commissioner's Order, is that

1 correct?

2 MR. MERRILL: Commissioner's Order,

3 correct.

4 H.O. LEUNG: Okay.

5 MR. MERRILL: If, if, if, if the child had
6 been immunized, that would have been in the immu-,
7 immunization registry.

8 H.O. LEUNG: Okay.

9 MR. MERRILL: That is, is something that is
10 maintained and that again, Ms. Kathleen checked and
11 which Dr. Rosen have checked --

12 H.O. LEUNG: Okay.

13 MR. MERRILL: -- appropriate to testify
14 about it. The medical necessity is a matter of --
15 the fact is --

16 H.O. LEUNG: Right.

17 MR. MERRILL: -- that there -- you know,
18 that the vaccine is safe and medically appropriate
19 for the vast majority of people.

20 H.O. LEUNG: Okay.

21 MR. MERRILL: When there are, in the rare
22 instances, medical exemptions or, or, or physicians
23 may say that a, a, a -- an immunization is medically
24 inappropriate, they reach out, we do review, we're
25 doing that for a couple of other clients there's been

1 no indication that this particular child has one of
2 the rare conditions that would make this vaccine
3 inappropriate for this child.

4 H.O. LEUNG: Okay. Mr. Siri?

5 MR. SIRI: I agree that the vast of
6 majority people received this -- the MMR product that
7 they're demanding. It's true.

8 H.O. LEUNG: But what we're going to do is
9 --

10 MR. SIRI: Most people -- most -- yeah.

11 H.O. LEUNG: I think we are going into the
12 facts of the case which --

13 MR. SIRI: Alright.

14 H.O. LEUNG: -- I -- this is just a
15 preliminary ruling. You have made an application to
16 request that the issuing officer appear. Before we
17 even get to the hearing, I have to --

18 MR. SIRI: I understand.

19 H.O. LEUNG: -- address this hurdle and I
20 have to make a ruling. That's why I've given you an
21 application and counsel. Based upon -- first off,
22 I'm going to just under OATH Trial and Hearing rules,
23 hearsay is permissible. It's really liberal. You
24 can have triple and double hearsay, it's really
25 liberal. So, the necessity of an issuing officer,

1 the reason why I asked you for the application is
2 that you have to make a good cause showing that the
3 issuing officer is required to appear in order for
4 you to get a fair and impartial hearing. In other
5 words, nothing that any of these parties that are
6 here today, including counsel for DOH, you need to
7 argue and establish can substitute for the in-person
8 testimony of the issuing officer and that's why I
9 asked you to make the application. And based upon
10 hearing both sides, I'm going to rule that the
11 hearing today will go forward. In other words, the -
12 - I'm going to rule that the issuing officer is not
13 required for you to get a fair hearing because what
14 she wrote on the, on the summons is, I can rule this,
15 establish a prima facie case. In other words, we
16 have people here to present the case and then you can
17 make an argument and testify on behalf of your client
18 and make arguments or call witnesses to rebut the
19 prima facie case. So, I'm going to make a ruling
20 that the issuing officer is not required for you to
21 get a fair and impartial hearing. I'm going to give
22 you one additional opportunity to -- because you look
23 perplex as to --

24 MR. SIRI: No, no. I -- I understand Your
25 Honor's ruling.

1 H.O. LEUNG: -- why -- no, no, but --

2 MR. SIRI: Yeah.

3 H.O. LEUNG: -- that's the standard which

4 is --

5 MR. SIRI: I, I --

6 H.O. LEUNG: -- inability of --

7 MR. SIRI: Yeah.

8 H.O. LEUNG: -- of your client and yourself

9 to get a fair and impartial hearing. Is there

10 anything that you want to add to supplement what you

11 have made, the application you have made?

12 MR. SIRI: Yeah. I just -- my, you know,

13 my -- I, I think I have made my, my arguments on the

14 record and --

15 H.O. LEUNG: Okay.

16 MR. SIRI: -- I just stand with those.

17 That --

18 H.O. LEUNG: Okay, no problem.

19 MR. SIRI: -- that I think the hearing

20 officer was necessary to establish medical

21 appropriateness but I understand Your Honor's ruling.

22 H.O. LEUNG: Okay.

23 MR. MERRILL: If I could add one thing,

24 Your Honor?

25 H.O. LEUNG: Sure.

1 MR. MERRILL: Along with the NOV, there was
2 a frequently asked question that was served as well
3 and everyone got an order. And in that, there were
4 questions and answers about, you know, submitting
5 proof of immunity or proof of a medical exemption and
6 we have not received anything from that person since
7 she was served the NOV.

8 H.O. LEUNG: Okay.

9 MR. SIRI: I believe, Your Honor, that
10 it's, it's the, you know, that that should have been
11 done before the viola-, meaning the violation is
12 issued. If it's not medically appropriate, it should
13 have been established or determined before the
14 violation was issued. Also, it's not as simple as
15 just, you know, you know, going to the doctors,
16 getting genetic testing, getting various -- doing the
17 type of work up that sometime is required.

18 H.O. LEUNG: Right.

19 MR. SIRI: It's quite burdensome. So, it's
20 not as simple --

21 H.O. LEUNG: Mr. Siri --

22 MR. SIRI: -- as just submitting a piece of
23 paper.

24 H.O. LEUNG: Mr. Siri, before we get into
25 the meat of the hearing --

1 MR. SIRI: Yes.

2 H.O. LEUNG: -- there is a couple other
3 things and this is -- it gets tedious but I have to
4 advise you that the penalty for this sole charge, if
5 you're found in violation, is \$1,000.

6 MR. SIRI: If my client is charged.

7 H.O. LEUNG: \$1,000 --

8 MR. SIRI: Yes.

9 H.O. LEUNG: -- for your client, right. If
10 your -- when I say your --

11 MR. SIRI: Yes.

12 H.O. LEUNG: -- the respondent, I'm sorry.

13 MR. SIRI: No problem.

14 H.O. LEUNG: And I need to advise you that
15 if you disagree with my written decision which you
16 will get within 30 days, you have a right to appeal
17 my decision. And if I dismiss the summons or reduce
18 it in anyway, the Department of Health has an equal
19 right to appeal my decision if they disagree with it,
20 okay, sir?

21 MR. SIRI: Yes.

22 H.O. LEUNG: Okay. Alright. We're going
23 to get to the meat of the hearing. Let me just --
24 okay. The summons alleges that on April 21, 2019 at
25 9:00 in the morning, during an inspection that

1 occurred at 585 Marcy Avenue, Apartment 2E, Brooklyn,
2 New York, a violation of New York City Health Code
3 3.05. The penalty for this violation, if found in
4 violation is \$1,000. The inspector wrote in response
5 to the active measles outbreak in certain parts of
6 Brooklyn, the New York City Commissioner of Health
7 declared a public health emergency on April 9, 2019
8 and published a Commissioner's Order pursuant to
9 Article 3 of the New York City Health Code ordering
10 all persons who live, work or attend school within
11 zip codes 11205, 11206, 11211 and 11249 to be
12 vaccinated against measles within 48 hours of the
13 order. On April 17, 2019, the New York City Board of
14 Health unanimously approved the resolution on
15 continuing the health -- public health emergency and
16 requirement that all persons living, working or
17 attending school in these affected zip codes to be
18 vaccinated against measles. The resolution further
19 provides that any person who is not vaccinated or any
20 parent and or guardian of a child who is not
21 vaccinated shall be fined unless they demonstrate
22 proof of immunity or that immunization is not
23 medically appropriate. A copy of the order and
24 resolution are attached to the summons for reference.
25 A review of department's record shows respondent's

1 child CR who is at least six months old lives at 585
2 Marcy Avenue, Apartment 2E, Brooklyn 11206 which is
3 located in one of the affected zip codes listed in
4 the order. On April 21, 2019, on review of the
5 Department Central Immunization Registry which
6 collects immunization records for all children
7 receiving vaccines in New York City and is required
8 to be updated by medical providers found that child
9 CR has no record of measles immunization, respondent
10 failed to vaccinate child CR or otherwise submit
11 acceptable proof of immunity in violation of the
12 order. I'm going to first turn to Department of
13 Health and ask if they have any documents or evidence
14 you want to present?

15 MR. MERRILL: Yes, Your Honor. I have and
16 I apologize for the, for the printing on this but I
17 have a, a copy of the order of the Commissioner which
18 was issued on April 9th in [unintelligible]
19 [00:12:43].

20 H.O. LEUNG: Okay.

21 MR. MERRILL: I also have, for your
22 records, it's a reference to the Board of Health
23 resolution dated April 17th and there is, there is
24 one page in there, there is only one.

25 H.O. LEUNG: Okay. I'm going to mark the

1 Commissioner's Order as Petitioner's 1 and the
2 Board's resolution as Petitioner's 2. I'm going to
3 show it to Mr. Siri and ask him that, do you have any
4 objection to those being admitted into evidence?

5 MR. SIRI: I, I have no objection other
6 than -- I have no objection, Your Honor.

7 H.O. LEUNG: Okay. Those are admitted into
8 evidence. Anything else from the Department of
9 Health?

10 **[Petitioner's Exhibits 1 and 2 admitted**
11 **into evidence.]**

12 MR. MERRILL: In terms of documents, no,
13 Your Honor.

14 H.O. LEUNG: Okay. Do you have any
15 testimony you want to provide?

16 MR. MERRILL: Yes, Your Honor. I think
17 we'll just, you know, again this was a child -- the
18 order was issued on April 9th, directing all
19 residents and children who did go to school and these
20 are, I believe who are to be immunized. After a case
21 investigation, this, this -- the registry which has a
22 record of all vaccination to children in the city was
23 checked on April 19th and the respondent's child was
24 found not to be vaccinated. The MO-, the, the NOV
25 was issued, the child has not submitted any proof.

1 There is no record of any immune-, immunity. There
2 is no record of any medical exemption and the child
3 to this date remains unvaccinated [unintelligible]
4 [00:14:01].

5 H.O. LEUNG: Okay. Is that all the
6 evidence you're going to present?

7 MR. MERRILL: Yes.

8 H.O. LEUNG: Okay. Siri, do you have any
9 cross examination before you present your argument or
10 evidence?

11 MR. SIRI: Do you want me to cross examine
12 the attorney because --

13 H.O. LEUNG: You can, you can ask the
14 attorney questions or --

15 MR. SIRI: Yeah. Because I -- the witness
16 -- I mean --

17 H.O. LEUNG: Go ahead.

18 MR. SIRI: It depends on the question we
19 may -- I mean, I may put it to her if that's alright.

20 H.O. LEUNG: It's, it's pretty liberal. If
21 your question is a medical question directly --

22 MR. SIRI: Yeah.

23 H.O. LEUNG: -- at the attorney, they're
24 allowed to, to have the doctor testify and then --

25 MR. SIRI: Yeah.

1 H.O. LEUNG: -- which addresses the
2 question and then you have an opportunity to ask the
3 doctor questions.

4 MR. SIRI: I would love, by the way, to
5 cross examine Tom but I'm not sure --

6 H.O. LEUNG: Okay.

7 MR. SIRI: -- that he, he would like that
8 too much.

9 H.O. LEUNG: I guess if you have any
10 question which is more appropriate. Yeah.

11 MR. SIRI: That -- Mr. Merrill, excuse me.
12 That said, I would -- I've got a few preliminary
13 arguments --

14 H.O. LEUNG: Sure.

15 MR. SIRI: -- in the form of motions to
16 dismiss as it were.

17 H.O. LEUNG: Okay.

18 MR. SIRI: And I can present those and --

19 H.O. LEUNG: You sure can, go ahead.

20 MR. SIRI: And then, and then I have -- and
21 then I would like to get into the meat --

22 H.O. LEUNG: Okay.

23 MR. SIRI: -- if, if, if, you know --

24 H.O. LEUNG: Sure.

25 MR. SIRI: If you don't believe those

1 should be ruled on, I don't know if you rule on those
2 on the spot or not, in same way that you ruled on the
3 application before, if you can rule on these
4 applications.

5 H.O. LEUNG: Yeah. None of your motions to
6 dismiss, I can rule on the spot, I have to make a
7 written decision on that. So, what we are going to
8 do is assuming -- we're going to go through the
9 entire possibilities.

10 MR. SIRI: Yeah.

11 H.O. LEUNG: In other words, factually
12 we're going to it.

13 MR. SIRI: Okay.

14 H.O. LEUNG: Or we're going to do it on
15 your procedural motions outside.

16 MR. SIRI: Okay.

17 H.O. LEUNG: So, go ahead.

18 MR. SIRI: That will make it long. Okay.
19 Alright, wonderful. So, in terms of the first, I
20 won't call it an application, this can't be ruled on
21 now, but the first, I guess, ground to dismiss this
22 summons. If you look at the summons, Your Honor, the
23 operative language at the end provides that, you
24 know, and I believe this is, you know, this is what
25 the violation is. If the respondents fail to vaccinate

1 child CR or otherwise submit acceptable proof of
2 immunity in violation of the, or, you used the word
3 order, order is a defined term in the summons, okay.

4 H.O. LEUNG: Right.

5 MR. SIRI: And the order was issued on
6 April 9th.

7 H.O. LEUNG: Yes.

8 MR. SIRI: And by operation of law, expired
9 on April 17th, because under the applicable charter
10 provision, an order of the Commissioner remains
11 effective until the next meeting of the Board of
12 Health. I have the -- I can just read the statutory
13 provision --

14 H.O. LEUNG: Okay.

15 MR. SIRI: -- since I have it here.

16 H.O. LEUNG: Okay. If I can just -- I
17 understand -- I, I think I understand what your
18 argument is. Your argument is that the order
19 expired. If you can address this while you address
20 your, your ultimate argument --

21 MR. SIRI: Sure.

22 H.O. LEUNG: -- is that the Section 3.05 as
23 alleged by the petitioner alleges in the alternative.
24 They are saying, you violated the Commissioner's
25 Order and the Health Board's resolution.

1 MR. SIRI: Respectfully, Your Honor, I
2 don't see where it says in this that it violated the
3 resolution.

4 H.O. LEUNG: Okay. Let me just see.

5 MR. SIRI: Which is completely different
6 than the order --

7 H.O. LEUNG: Sure.

8 MR. SIRI: -- substantive in many ways.

9 H.O. LEUNG: You're right in a sense it's
10 that -- okay. Can you address the issue that the --
11 they are alleging that the Board on April 17th, if
12 you look at the summons and I'm just -- I'm not
13 making the argument for them. I just want you to
14 address it just to save time because it's a question
15 that I'm going to ask you ultimately. On April 7th -
16 - it says on the summons, on April 17, 2019, the New
17 York City Board of Health unanimously approved the
18 resolution continuing the public health emergency and
19 requirements. And you are saying that --

20 MR. SIRI: Yeah.

21 H.O. LEUNG: -- that the continuing of the
22 health emergency is one thing, but the actual order
23 to comply expired on April 17th.

24 MR. SIRI: Well, I -- I'm actually going to
25 say two things.

1 H.O. LEUNG: Yeah.

2 MR. SIRI: The first one, Your Honor, is
3 that it only alleged violation of the order and the
4 order, despite -- even though this vio-, this
5 violation, if you look at it, it says that it
6 continues the public health emergency. It doesn't
7 say continued by the way of the order. And when you
8 actually look at the order and the resolution,
9 nothing in the resolution continued the order. And
10 in fact, they apply to different ages, to different
11 people in different situations, you know, under the
12 charter, okay, Section -- Article 3 --

13 H.O. LEUNG: Go ahead, Counsel, you can
14 continue --

15 MR. SIRI: Okay, no problem, I, I have, I -
16 -

17 H.O. LEUNG: No, no, go ahead, I'm
18 listening. Yeah.

19 MR. SIRI: You are, you are more talented
20 than I am.

21 H.O. LEUNG: Yeah. Yeah, go ahead.

22 MR. SIRI: So, I, I've got -- it's -- in
23 Article 3, Section 3.0 of the charter, it says that,
24 you know, and the Commissioner's Order is that, that
25 the exercise of that power shall be "Any such

1 exercise of the power shall be effective only until
2 the next meeting of the Board," okay? So, by the
3 operation of law, it ends at the next Board meeting
4 and now, the Section 3.0 says the Board may, may
5 continue or rescind, okay, the Commissioner's, let's
6 just call it order, okay? They have that choice.
7 They could have continued or rescind it,
8 interestingly it doesn't say modified. It could have
9 said, they could have done it but they didn't. The
10 resolution, nowhere therein, says they are continuing
11 or rescinding the order. Instead, they, they did
12 something of their own making. And they have every
13 right. They can I guess do that but what, what they
14 didn't do was provide, you know, that they are
15 continuing the order nor provide, you know, they are
16 rescinding the order. And the only thing that,
17 that's been alleged in the violation excuse me, the
18 summons is a violation of the order. And that order
19 by its terms expired, by operation of law expired on
20 the 17th of April. The violation at issue here, Your
21 Honor, was issued -- was for an occurrence on April,
22 April 21st which would had been four days after the
23 expiration of the order. Hence, there cannot be a no
24 viol-, it cannot be a violation of an order on that
25 date since it was no longer in existence.

1 H.O. LEUNG: Okay. I'm going to turn to
2 counsel for DOH and ask, how do you respond to the
3 argument?

4 MR. MERRILL: So, I am going to start with
5 the, the citation, the Health Code which is the cited
6 3.05. It says it's a violation of the order of the
7 Board, permission [unintelligible] [00:21:01]
8 departments 3.05 can be a violation of the
9 Commissioner's Order or it can be a violation of the
10 DOH, any order [unintelligible] [00:21:07].

11 H.O. LEUNG: And you are referring to the
12 actual statute 3.05?

13 MR. MERRILL: Correct, the Health Code
14 section, yes.

15 H.O. LEUNG: Okay.

16 MR. MERRILL: That's correct. And then in
17 terms of what power that the, the Commissioner
18 exercised pursuant to the emergency was the Board's
19 power which existed to declare an instances of, and
20 under 17148 and 42 I believe of the Health Code.
21 The, the, the Commissioner did that on April 9th.
22 You are correct. And her power to declare that an
23 emergency exists only until the Board meeting but in
24 the Board meeting, it issued an order that requires
25 all residents of Williamsburg to be vaccinated. The

1 fact that it may have the Board, the Board in the
2 exercise of its authority under the Administrative
3 Code of the charter, it may have differed slightly in
4 the language of that order. It doesn't change the
5 fact that there is a valid Board of Health order
6 issued on April 9th. No, that was the Commissioner's
7 Order. On April 15th, whatever date the board met.

8 H.O. LEUNG: 17th.

9 MR. MERRILL: 17th, that required all
10 residents to be vaccinated and that this person
11 violated that order as charged in the order -- in the
12 NOV as, as required by the Health Code Section 3.05.

13 MR. SIRI: I don't, I don't dispute at all
14 that Section 3.05 is exactly as, as, as opposing
15 counsel stated. Yeah, it per-, it permits issuing
16 violations for violating any order or resolution,
17 anything. It could be -- it could have been for
18 having rats in your, in your restaurant, right? But
19 you're only going to be charged, you have to give
20 notice of what you are charged and the charging
21 language here was not for violating the resolution,
22 it was for violating the order.

23 H.O. LEUNG: Okay.

24 MR. SIRI: That's what it covers --

25 H.O. LEUNG: How do you respond to that,

1 Counsel? Go ahead.

2 MR. SIRI: May, may I make one more point,
3 Your Honor?

4 H.O. LEUNG: Yeah.

5 MR. SIRI: And I think it's very, you know,
6 it's very telling that counsel kept talking about
7 the, you know, the resolution applies to residents,
8 right? Well, you know, it's a, it's a great point to
9 show you the difference between the order and the
10 resolution because in the order, to be sure, counsel
11 is correct. It did apply. It did apply to
12 residents. It specifically provides that it applies
13 to any person who lives, works or resides within
14 these certain zip codes but if you look at the
15 resolution, it didn't include residents. It only
16 included the, the people who live or work --

17 H.O. LEUNG: Where are you looking at on
18 the resolution, just what paragraph you're looking?

19 MR. SIRI: Absolutely. So, in the, in the
20 order, if you look at the first order paragraph --

21 H.O. LEUNG: Mm-hmm.

22 MR. SIRI: -- okay, and the very first
23 sentence says that any person who lives, works or
24 resides --

25 H.O. LEUNG: Right.

1 MR. SIRI: -- it showed on the second page.

2 H.O. LEUNG: Got you. So, --

3 MR. SIRI: First -- it's on first -- second
4 page, the operative ordered language of, of the order
5 --

6 H.O. LEUNG: I got you, I got you --

7 MR. SIRI: Okay. And then, and then and go
8 to the resolution.

9 H.O. LEUNG: Right.

10 MR. SIRI: And you go and you look at the -
11 - to the resolved language and you please look at the
12 second resolve paragraph. It says that the Board
13 hereby declares that any person who lives or works
14 within the affected zip codes. They left out people
15 who are resident, meaning, if you reside in there and
16 you have left, you are not living there, right? So,
17 if you went upstate, you're good, where the order did
18 apply to people who resided there. So, even if you
19 left, you apparently were still in violation
20 amazingly. I mean, so, you know, it -- it's a great,
21 you know, it's a great highlight to how -- what the,
22 what the Board did was different with what the, what
23 the Commissioner did.

24 H.O. LEUNG: Okay. How do you -- I'm just
25 looking at it briefly to the second to last resolved

1 paragraph --

2 MR. SIRI: Please, yes.

3 H.O. LEUNG: -- of the resolution.

4 MR. SIRI: That's right.

5 MR. MERRILL: I'm looking at the current,
6 the fourth one, the last one in this page, Your
7 Honor, it says whereas the Board did hereby declare
8 that any person who lives or work within the affected
9 zip codes shall be vaccinated.

10 H.O. LEUNG: Okay. Just tell me what you
11 are reading. Is it the resolution?

12 MR. MERRILL: I'm reading the order, I'm
13 reading the order. I mean the Board of Health
14 resolution.

15 H.O. LEUNG: Okay. And which reso-, --

16 MR. MERRILL: On the second page.

17 H.O. LEUNG: Okay.

18 MR. MERRILL: At the very bottom.

19 H.O. LEUNG: Under resolved?

20 MR. MERRILL: Correct.

21 H.O. LEUNG: This -- which, first, second,
22 third, fourth?

23 MR. MERRILL: Second resolve.

24 H.O. LEUNG: Second resolve?

25 MR. MERRILL: Yes.

1 H.O. LEUNG: Okay.

2 MR. MERRILL: And resolve that the Board of
3 Health hereby declares that any person who lives or
4 works within the affected zip codes shall be
5 vaccinated against measles. So, it does and that's
6 residents, people who live or work within the -- and
7 that's what it goes on to schools. So, it does cover
8 people living there.

9 H.O. LEUNG: Right. He pointed that out
10 and how do you want to respond to it?

11 MR. SIRI: Right. I think there is a
12 distinct between children and adults, right? So, --

13 MR. MERRILL: Any person, I mean I think a
14 person is a person. I don't --

15 MR. SIRI: Well, I -- well, the way I read
16 is, is that it, it, it goes into -- it's a semantical
17 point to be sure, right?

18 H.O. LEUNG: Okay.

19 MR. SIRI: But the, the operative point.

20 H.O. LEUNG: Okay. I, I understand your
21 argument.

22 MR. SIRI: You understand the argument.

23 H.O. LEUNG: I understand your argument.
24 Counsel for DOH is, is pointing to the second resolve
25 and you are pointing to second resolve saying you

1 interpret it one way and they interpret it one way,
2 okay.

3 MR. SIRI: Right. But, but, but the, but
4 the, but the obviously more important point is that,
5 you know, the vio-, alleged violation is for the
6 order, the order was not in effect on the date of the
7 issuance of the summons and it wasn't by anything, I
8 mean I, I don't see any language in the resolution
9 saying the order is hereby continued.

10 MR. MERRILL: To respond to that, if you go
11 into the middle of the NOV, I mean there is some type
12 of discussion in the resolution. We're getting to
13 the fact that on April 17th, the Board approved the
14 resolution, continuing the public health emergency
15 and the requirement that all persons living, working
16 or attending school on these affected zip codes be
17 vaccinated against measles. The resolution further
18 advised that any person who is not vaccinated or
19 parent or guardian of a child who is not vaccinated
20 shall be fined unless they demonstrate proof of
21 immunity. I think the NOV clearly put somebody on
22 notice that the resolution is in effect and are --
23 and they are being charged with violating the
24 resolution.

25 MR. SIRI: I did not hear anywhere in there

1 that the resolution was continued.

2 H.O. LEUNG: Okay.

3 MR. SIRI: That the order was continued
4 from what we just read. I mean I, I --

5 MR. MERRILL: I think, I think there is a
6 technical again, 3.05 --

7 MR. SIRI: I don't think that's 100
8 percent. Well, I think that if you are going to
9 charge people and require them to inject something
10 into their children's body, you should be clear
11 about, you know, whether the order is continued. I
12 mean, you know, the section, the charter is clear.
13 They can continue it or they can rescind it. The,
14 the Board didn't choose either of those. It chose to
15 issue -- I'll give you a few examples, just, just a
16 few quick examples that I do know of clear
17 differences. I, I, I jumped on the resident point
18 but I will -- so, for example, in the order, okay,
19 the, the order apply to those over six months of age.
20 The resolution included those of six months of age.

21 H.O. LEUNG: And wait, can, can you just
22 point to --

23 MR. SIRI: Absolutely.

24 H.O. LEUNG: Yes.

25 MR. SIRI: So, if you look at the, if you

1 look at the order in the sec-, it is further ordered
2 that the parent or guardian of any child older than
3 six months of age --

4 H.O. LEUNG: What paragraph are you
5 referring to?

6 MR. SIRI: It's the pre-number paragraph,
7 the second last paragraph of the order. It is
8 further ordered --

9 H.O. LEUNG: Okay. I see that.

10 MR. SIRI: -- older than six months and
11 then --

12 H.O. LEUNG: Any child older than six
13 months of age?

14 MR. SIRI: Right.

15 H.O. LEUNG: Okay.

16 MR. SIRI: And then if you look at the
17 resolution, it says that and this is in the third to
18 last resolve paragraph, I don't know the technical
19 term for that, [unintelligible] [00:28:25] third last
20 paragraph.

21 [OFF MIC CONVERSATION]

22 MR. SIRI: Third to last resolve paragraph,
23 it says that the parent or guardian of any child six
24 months of age or older. So, you have a difference in
25 terms of the age of that, it applies to between the

1 resolution and the order.

2 H.O. LEUNG: So, you are saying that one
3 day difference between a child six --

4 MR. SIRI: Month difference.

5 H.O. LEUNG: I'm sorry, say one more time?

6 MR. SIRI: Month difference.

7 H.O. LEUNG: Month difference.

8 MR. SIRI: So, it doesn't -- the order
9 apply -- did not apply to six month olds which we
10 have a number of folks.

11 H.O. LEUNG: Well, if a child is six months
12 of age or older, I mean, the estimate that child to
13 be a 100 -- whatever how many days six months is.
14 Are you saying that the statute is written -- has to
15 jump like month increments, I mean --

16 MR. SIRI: No, I'm saying that they're just
17 --

18 H.O. LEUNG: Six months and a day --

19 MR. SIRI: I'm just saying they are
20 different.

21 H.O. LEUNG: Right.

22 MR. SIRI: I'm saying they're different.
23 I'm saying what the Board did was different than what
24 the order did. I'll give you some other change
25 meaning.

1 H.O. LEUNG: Go ahead.

2 MR. SIRI: The order said --

3 H.O. LEUNG: Okay, I'm going to need --

4 MR. SIRI: Yeah.

5 H.O. LEUNG: -- the record to reflect that
6 I, I understand your argument regarding the six
7 months reference in the order and the six months
8 reference in the resolution.

9 MR. SIRI: Is it clear that it's -- so, so
10 the order did not apply to six months old. Meaning,
11 they couldn't issue a violation just -- a child that
12 was six months of age under the order for not having
13 an MMR --

14 MR. MERRILL: You mean under the
15 resolution?

16 MR. SIRI: Under the or-, under the or-,
17 under the order.

18 MR. MERRILL: Okay.

19 MR. SIRI: The order was six month -- was
20 older than six months. The resolution said six
21 months or older so the --

22 MR. MERRILL: So, the resolution brings in
23 one, one extra date.

24 MR. SIRI: Resolution does allow providing
25 violations to those who are six months of age.

1 H.O. LEUNG: Okay. So, the --

2 MR. SIRI: But the order doesn't.

3 [CROSSTALK]

4 H.O. LEUNG: And if we tie it all in,
5 Counsel, the significance of that is what?

6 MR. SIRI: Well, for this client -- well, I
7 have violation specific.

8 H.O. LEUNG: Right.

9 MR. SIRI: But, but for this client --

10 H.O. LEUNG: Yeah.

11 MR. SIRI: -- the significance is that the
12 -- that is that, is that the Board didn't just --
13 first of all, it never says in the resolution, we are
14 continuing the order.

15 H.O. LEUNG: Right, I understand that --

16 MR. SIRI: And the second, and, and there
17 are differences. It didn't just --

18 H.O. LEUNG: Right.

19 MR. SIRI: -- say, okay what you did in the
20 order, we are continuing it. No, it said, okay,
21 we're going to have different resolve language. One
22 is, we're going to apply different age group. Two is
23 and this also is critical, the, the order refers,
24 calls the people who are not receiving MMR the
25 nuisance, okay?

1 H.O. LEUNG: Say, say that one more time.

2 MR. NAME: The order of -- the order
3 characterizes the nuisance as those who haven't
4 received an MMR shot.

5 H.O. LEUNG: What paragraph are you
6 referring to?

7 MR. SIRI: So, it's the -- okay. So, it's
8 the second to last where as clause in the order.

9 H.O. LEUNG: Okay.

10 MR. SIRI: I find that the presence of any
11 person at Williamsburg lack in the MMR vaccine...is
12 therefore a nuisance.

13 H.O. LEUNG: Okay. As defined in New York
14 City Administrative Code 17-142, okay. And what do
15 you want to point out --

16 MR. SIRI: And then, and then in the --

17 H.O. LEUNG: -- that's different in the
18 order or in the resolution?

19 MR. SIRI: And then in the resolute-, and
20 in the resolution, if you look at the first resolve
21 paragraph, it says that the outbreak poses a public
22 nuisance. So, the, the, you know, the res-, I'll let
23 you find --

24 H.O. LEUNG: No, no, I found, I found it.

25 MR. SIRI: So, so, so the, you know, so

1 the, the Board characterizes the outbreak as a
2 nuisance. The, the order characterizes the folks who
3 didn't receive MMR vaccine as the nuisance. Just,
4 just another example of, of the difference, I'll give
5 you another, I'll give you another example. The, the
6 Order did not --

7 H.O. LEUNG: Counsel, I'm going to ask you
8 to do two things.

9 MR. SIRI: Yeah.

10 H.O. LEUNG: Number one, I understand that
11 there is differences in the language between the
12 order and the resolution. I want you to go one step
13 further and then give me a conclusion --

14 MR. SIRI: Yes.

15 H.O. LEUNG: -- and therefore --

16 MR. SIRI: Okay. I'll give you --

17 H.O. LEUNG: -- the significance of the
18 difference in the language, how, how, how it supports
19 your argument.

20 MR. SIRI: Absolutely.

21 H.O. LEUNG: Go ahead.

22 MR. SIRI: Can I just make -- point out for
23 the record just another --

24 H.O. LEUNG: Sure. Okay. Yeah.

25 MR. SIRI: The, the, the order did not

1 apply to schools, preschools or childcare.

2 H.O. LEUNG: Okay. What are you looking at
3 here? Just point to --

4 MR. SIRI: Sure. So, if you look at the
5 order of language on the order, if you look at the
6 two order paragraph, that doesn't say anything about
7 school, preschool, childcare. It just says people
8 who live, work or reside, okay?

9 H.O. LEUNG: Okay.

10 MR. SIRI: Versus look at the third to last
11 resolve paragraph in the resolution, it does include
12 those who are attending school, preschool or child
13 care. So, you didn't have to live, work or reside in
14 the affected zip codes.

15 H.O. LEUNG: Okay.

16 MR. SIRI: Okay?

17 H.O. LEUNG: I understand your argument.
18 Go ahead.

19 MR. SIRI: Okay. Those are few other
20 differences.

21 H.O. LEUNG: Sure. You want to --

22 [CROSSTALK]

23 MR. SIRI: Okay. I'll just get -- I'll get
24 -- yeah.

25 H.O. LEUNG: No, no, whatever, whatever you

1 want to point, I'm not going to cut you short.

2 MR. SIRI: Sure.

3 H.O. LEUNG: What, what other things you
4 want to point out that's a difference between them?

5 MR. SIRI: Okay. And, and, and so the
6 order provided for criminal fines, forfeiture and --

7 H.O. LEUNG: Where are you, where are you
8 referring to?

9 MR. SIRI: Absolutely. So, the last page
10 of the order under the warning.

11 H.O. LEUNG: Right.

12 MR. SIRI: It provides for criminal fines,
13 forfeiture and imprisonment for not complying with
14 the order.

15 H.O. LEUNG: What paragraph are you
16 referring to?

17 MR. SIRI: Under the warning, very -- flip
18 that page over.

19 H.O. LEUNG: Okay.

20 MR. SIRI: They're, they're saving trees,
21 that's good.

22 H.O. LEUNG: Yes.

23 MR. SIRI: In the first paragraph under
24 warning.

25 H.O. LEUNG: Got you.

1 MR. SIRI: Okay. The resolution does not
2 provide for forfeiture, a criminal fines or
3 imprisonment.

4 H.O. LEUNG: Okay. Well, let me just say
5 this.

6 MR. SIRI: Yeah.

7 H.O. LEUNG: The warning isn't, I mean, I'm
8 just making an observation. How do you address the
9 fact that this warning isn't the law? I mean, it's
10 just pointing out what the law provides and it's
11 almost like a label saying, hey, the law provides
12 that. I mean, the absence of this warning doesn't
13 mean that the law isn't in effect and the presence of
14 this warning doesn't make the law, in fact the law is
15 what the law is.

16 MR. SIRI: Yeah. Well, respectfully, the
17 Health Code provides discretion to the Health
18 Department to choose the penalty.

19 H.O. LEUNG: Right. So, you're saying that
20 the presence of this warning which gives you the
21 warning that this is a misdemeanor [unintelligible]
22 [00:34:39] that's in the order and the absence of
23 that warning in the resolution is what you're
24 pointing out to, is that what you're pointing out?

25 MR. SIRI: I'll point out the following

1 words --

2 H.O. LEUNG: Sure.

3 MR. SIRI: -- but before it says and it's
4 not just this is the law.

5 H.O. LEUNG: Right.

6 MR. SIRI: It says failure to comply with
7 this order is obliged [unintelligible] [00:34:55] and
8 a misdemeanor for which may be subject to these
9 things.

10 H.O. LEUNG: Right. And where is the
11 authority --

12 MR. SIRI: So, it wasn't just a general
13 law.

14 H.O. LEUNG: Right.

15 MR. SIRI: The point is, is that that is
16 what was being threatened under the order --

17 H.O. LEUNG: Right.

18 MR. SIRI: -- absent from the resolution.
19 Just another -- there are other distinctions. I will
20 -- I, I can see --

21 H.O. LEUNG: No, no, no, I'm not --

22 MR. SIRI: I can, I can get to the end if
23 you want.

24 H.O. LEUNG: No, no, you can, you can -- I
25 just have to -- because I have to write the decision,

1 I have to understand your argument.

2 MR. SIRI: Yeah, sure.

3 H.O. LEUNG: And that's the --

4 MR. SIRI: So, that is another -- is there
5 -- so that is another obviously what the penalty is,
6 is --

7 H.O. LEUNG: Can --

8 MR. SIRI: Yeah.

9 H.O. LEUNG: Can you just explain to me how
10 you're pointing out differences between the order and
11 the resolution.

12 MR. SIRI: Yes.

13 H.O. LEUNG: To what end is that --

14 MR. SIRI: Yeah.

15 H.O. LEUNG: -- supporting your motion to
16 dismiss? What is the ultimate argument?

17 MR. SIRI: Absolutely. What it points out
18 is this. I believe counsel is saying that, well, you
19 know, the resolution talks about the order and so it
20 continued it somehow. But the resolution never says
21 it continues it. And not only does it not say that
22 it continues it, which is critical to continue it in
23 order.

24 H.O. LEUNG: Right.

25 MR. SIRI: You have to say you continue it

1 or they could say withdrew it, they didn't do either
2 of those, right? It actually has all kinds of
3 differences. The Board chose to do something
4 different and that's fine, they chose to do that.
5 And so, you have a resolution that stands on its own
6 and you have an order that stands on its own, okay?
7 And this resolution did not continue this order.
8 This order --

9 H.O. LEUNG: Can I ask you a question?

10 MR. SIRI: -- went away on April 17th.
11 This violation is --

12 H.O. LEUNG: Can the resolution add things
13 and do things and also continue the order, in your
14 opinion?

15 MR. SIRI: If you look, and it's not my
16 opinion.

17 H.O. LEUNG: Uh-huh.

18 MR. SIRI: If you look at the, at the
19 charter provision, Section 3.01, it says that the
20 Board may continue or rescind as soon as the
21 Commissioner's Order.

22 H.O. LEUNG: Okay.

23 MR. SIRI: It doesn't say modify. It
24 doesn't say amend. It says continue or rescind. And
25 it could have chose to do that --

1 MR. MERRILL: What part are you reading
2 from?

3 MR. SIRI: Section 3.01 general powers of
4 the department.

5 MR. MERRILL: It's not charter itself
6 though.

7 MR. SIRI: Sorry.

8 MR. MERRILL: Okay.

9 MR. SIRI: It's under the Administrative
10 Code.

11 MR. MERRILL: No, it's not.

12 MR. SIRI: It's under the rules --

13 MR. MERRILL: It's the health code.

14 H.O. LEUNG: It's the health code.

15 MR. SIRI: It's the health code. Well,
16 they can leave here and change it if they want, I
17 guess.

18 MR. MERRILL: There is no need to because
19 I'll, I'll clarify it a minute. I'll read that out.

20 H.O. LEUNG: Okay. Counsel, you said a lot
21 and I'm going to --

22 MR. SIRI: Yes, please.

23 H.O. LEUNG: We have to give before we
24 forget everything you said because you -- there is
25 whole -- what -- do you want to address about it?

1 MR. MERRILL: Sure, yes.

2 H.O. LEUNG: Go ahead.

3 MR. MERRILL: I think Mr. Siri is coming at
4 this a little backwards because if you look at 3.01,
5 the -- he -- what he's saying, his position is the,
6 the commit-, the Commissioner can act in an emergency
7 and then the Boards' hands are tied to do only what
8 the Commissioner has done or to rescind it in its
9 entirety. But if you look at 3.01(d), what that does
10 is it gives the Commissioner the authority in an
11 emergency to step up and to act and to use the
12 Board's powers because of the emergency to, among
13 other things, exercise its power to prevent,
14 mitigate, control or evade an emergency, provided
15 that that will be effective until the next Board of
16 Health meeting. And the purpose, if you look at it,
17 the, the -- she is playing the role of Board, the
18 Board then comes in and the Board, there is nothing
19 that limits the Board's ability or, or authority and,
20 and the ability to take whatever it deems to be
21 appropriate action to evade, you know, to, to address
22 that emergency in that order. So, I, I agree that
23 the order is -- are not, not a 100 percent identical.
24 There are minor differences in there, but the bottom
25 line is what, what, what is -- what was true and it

1 can't be disputed. There was a resolution in effect
2 by the Board of Health under its power to abate
3 nuisances in the city directing all residents of
4 Williamsburg to be immunized, that was violated. And
5 it is in the NOV. I'll point out in terms of what
6 are the differences here, you know, in terms of the,
7 the criminal language which is standard language we
8 have in all our orders even though typically
9 [unintelligible] [00:38:57]. The reason that's not
10 in there anymore is that we are challenged. The
11 Board's authority was challenged in the Appellate --
12 in the court, in Supreme Court. And in the course of
13 that argument when, when we were claiming we were
14 going to be arresting people, we said, no, we never
15 intended, we are going to be enforcing that, that
16 civilly. And that was going on at the same time
17 while we were going, you know, between the, the order
18 and the Board's actions. And so, the Board's action
19 doesn't reference criminal -- reference sanctions
20 because we, we acknowledged and when we were -- when
21 the authority of the Board was being challenged and
22 when the authority of the Board were being upheld by,
23 by the Supreme Court that we were going to be
24 enforcing this similarly. So, the bottom line is
25 there is a -- I just don't agree with Mr. Siri that

1 the order that there is anything that requires the
2 Board's resolution/order to be identical and informed
3 to the Commissioners because it has the authority to
4 choose using its authority to take the actions that
5 it deems appropriate to evade a nuisance. And it did
6 that when they issued its resolution continuing the
7 requirement that people be vaccinated against measles
8 and that's what this person violated.

9 MR. SIRI: Yeah. Your Honor, I, I think
10 maybe we are agreeing then that the order was nullity
11 on the 17th and all that remained --

12 MR. MERRILL: Was an order of the Board.

13 MR. SIRI: Was a resolution of the Board.

14 MR. MERRILL: Which is an order, which
15 directs all people. It was published --

16 MR. SIRI: And the or-, but that's not
17 what's alleged in this.

18 MR. MERRILL: It is alleged.

19 MR. SIRI: They are alleging a violation of
20 the order which is only the Commissioner's Order and
21 not the resolution.

22 MR. MERRILL: The, the NOV pleads and says
23 you, you are required to be vaccinated or -- by the
24 Board of Health resolution 3.05 references resolution
25 -- the Board, Board action, she violated the Board

1 action.

2 MR. SIRI: Yeah, the, the violation -- the
3 summons clearly says respondents failed to vaccinate
4 child or submit acceptable proof in violation of the
5 Order, and Order is defined as the Commissioner's
6 Order and that was a nullity at the time that this
7 summons was issued irrespective of this, you know,
8 the, the, the --

9 H.O. LEUNG: Okay.

10 MR. SIRI: -- the nuances are going to be
11 modified, they are going to do it. The point is that
12 order is gone.

13 H.O. LEUNG: Do you want to respond to that
14 or --

15 MR. MERRILL: I think -- I, again, I think
16 there is semantics here. The resolution is, is an
17 order. And so, it's going to be --

18 H.O. LEUNG: Okay.

19 MR. MERRILL: And, and if you read this
20 NOV, it clearly puts you on notice that there is a
21 requirement that you be vaccinated, that you are
22 violating. So, that to me, you know, again, we can
23 just, you know, the, the fact of the matter is the
24 resolution, if you use the resolution, you use the
25 order, there was a requirement that you be vaccinated

1 that's in this NOV that wasn't complied with and
2 there -- and 3.05 makes it clear that the Board, the
3 Board directs you to take action and you violate
4 that, that is a violation of 3.05.

5 MR. SIRI: I, I think the violation alleges
6 clearly what they are alleging was violated and it
7 only says order.

8 H.O. LEUNG: Okay. Before I -- I think I
9 have enough to make a decision. Before, I just want
10 to clarify factually, Mr. Siri, there was an in --
11 there was an argument you made regarding the child
12 being either, the order -- the difference between the
13 order and the resolution, one being six months or
14 older and the other one being --

15 MR. SIRI: I think that's a secondary
16 point.

17 H.O. LEUNG: No, no, but I need --

18 MR. SIRI: It's the primary -- yeah.

19 H.O. LEUNG: I need to establish for the
20 record, when you -- do you believe that your client,
21 the -- again your client, I don't know if it's a
22 parent or the child, but do you believe that the
23 child at issue at here falls factually within that in
24 the -- in other words, do you believe that at the
25 time of the summons that the child was either exactly

1 at six months old or six month plus one day where it

2 --

3 MR. SIRI: Well, I'm not making that
4 argument for my client.

5 H.O. LEUNG: No, no, I just need --

6 MR. SIRI: Yeah, you know, this client was
7 not six months of age.

8 H.O. LEUNG: Or six months and one day.

9 MR. MERRILL: Right.

10 H.O. LEUNG: Okay.

11 MR. SIRI: No, that, that's not the issue.

12 H.O. LEUNG: Alright.

13 MR. SIRI: The issue is that they are
14 charging that my client violated an order on the --
15 on, on the 23rd -- on the 21st of April but that
16 order was a nullity by the April 17th.

17 H.O. LEUNG: Okay.

18 MR. SIRI: That's the, that's the, that's
19 the issue.

20 H.O. LEUNG: Okay.

21 MR. SIRI: The rest of it is window
22 dressing.

23 H.O. LEUNG: Right.

24 MR. SIRI: Everything else.

25 H.O. LEUNG: So, I have enough to make a

1 decision. I am just going to summarize the -- I'm
2 going to allow both sides to make arguments. The
3 issue in this case appears to be whether or not the -
4 - first off, Petitioner's 1, which is the order of
5 the Health Department Commissioner issued on April 9,
6 2019, which everyone agrees remained in effect until
7 the next scheduled Board of Health meeting, which was
8 on April 17th. Petitioner's 2 is the Board of Health
9 resolution dated April 17th. There is a dispute as
10 to whether the language of the Board of Health
11 resolution, number one, continued the order issued by
12 the Health Commissioner. The record should reflect
13 that Counsel, Mr. Siri has made an argument that
14 there is no explicit language in the resolution P2
15 which directly states in summons substance that the
16 Commissioner's Order is hereby continued. There is
17 nothing expressed in that and that's agreed that from
18 the Health Department that there is nothing
19 expressed. The issue as to whether or not it's
20 continued is a factual issue, ire-, irrespective of
21 whether or not Department of Health concedes that. I
22 understand your argument. The second issue is
23 whether or not the resolution on its own,
24 Petitioner's 2 was something that was alleged in the
25 summons putting respondent on notice that he needed

1 to comply with P2, the resolution. And I understand
2 both sides arguments here and I'll allow both sides
3 to make argument as to --

4 MR. MERRILL: Okay, the charter.

5 H.O. LEUNG: Mr. Siri, is there anything
6 you want to add?

7 MR. SIRI: Yeah. Just to say that the, the
8 the -- even though it references the resolution, it
9 in fact -- by referencing the resolution, it defines
10 resolution in this violation. It specifically
11 defines the word, what -- if you look at the
12 violation --

13 H.O. LEUNG: Just, just for the record,
14 what are you reading and what are you pointing out?

15 MR. SIRI: Right. So, when you look at the
16 summons --

17 H.O. LEUNG: Okay.

18 MR. SIRI: -- 30198-, --

19 H.O. LEUNG: We are looking at the summons.

20 MR. SIRI: So, looking at the summons --

21 H.O. LEUNG: Okay. Go ahead.

22 MR. SIRI: -- you can see it starts by
23 refre-, referencing the Commissioner's Order and it
24 defines the word order. Do you see that?

25 H.O. LEUNG: Just, just tell -- state the

1 language you are reading to.

2 MR. SIRI: Yeah. Absolutely.

3 H.O. LEUNG: Okay.

4 MR. SIRI: It says -- so, the violation
5 description begins --

6 H.O. LEUNG: Yeah.

7 MR. SIRI: -- in response to the active
8 measles outbreak in certain parts of Brooklyn, the
9 New York City Commissioner of Health declared a
10 public health emergency on April 9, 2019 and
11 published a Commissioner's Order.

12 H.O. LEUNG: Right.

13 MR. SIRI: Defined as order (order).

14 H.O. LEUNG: Right.

15 MR. SIRI: So, order means the
16 Commissioner's order that expire by Provision of Law
17 on April 17th, I believe there is no dispute about
18 that.

19 H.O. LEUNG: Can, can I stop --

20 MR. SIRI: Yeah.

21 H.O. LEUNG: -- you there? And I
22 understand your argument.

23 MR. SIRI: Yes.

24 H.O. LEUNG: Can you address this argument
25 because ultimately, I have to write a decision. And

1 this is something that I want both sides to address.
2 The following sentence on the summons which is the
3 second full sentence, on April 17, 2019, the New York
4 City Board of Health unanimously approved the
5 resolution continuing the public health emergency and
6 requirement that all persons living, working or
7 attending schools in these effected zip codes be
8 vaccinated against measles.

9 MR. MERRILL: And I have had the other next
10 sentence too, Your Honor, that one as well which is
11 the resolution further provides that any person who
12 is not vaccinated or the parent or guardian of the
13 child who is not vaccinated shall be fined unless
14 they demonstrate proof of immunity or that
15 immunization is not medically appropriate. It seems
16 like an order.

17 H.O. LEUNG: So -- I, I guess the question
18 I have is --

19 MR. SIRI: But you keep -- I, I would like
20 to continue reading it, Your Honor.

21 H.O. LEUNG: Yeah, sure.

22 MR. SIRI: Because it goes on and it says -
23 -

24 H.O. LEUNG: Well, well --

25 MR. SIRI: -- and, and, and I agreed --

1 H.O. LEUNG: No, no, I understand Mr. Siri.

2 MR. SIRI: And it -- yeah.

3 H.O. LEUNG: Yeah, go ahead.

4 MR. SIRI: Yeah, and, and then it goes on
5 and says and a review of the records and then it ends
6 by saying the respondents failed to vaccinate
7 otherwise acceptable proof of immunity in violation
8 of the order.

9 H.O. LEUNG: Correct.

10 MR. SIRI: It is alleging a violation of
11 the order. That is all that this violation
12 description --

13 H.O. LEUNG: Mr. Siri, I understand your
14 argument that a portion of the allegation on the
15 summons refers only to the order. What I would like
16 you to address and my question was --

17 MR. SIRI: Yes.

18 H.O. LEUNG: -- the following sentences.
19 On April 17, 2019, the New York City Board of Health
20 unanimously approved a resolution, --

21 MR. SIRI: That's right.

22 H.O. LEUNG: -- and resolutions in
23 paragraph.

24 MR. SIRI: That's right.

25 H.O. LEUNG: Continuing the public health

1 emergency and requirement that all persons living,
2 working or attending schools in these effected zip
3 codes be vaccinated against measles. The resolution
4 further provides that any person who is not
5 vaccinated or the parent and or guardian of the child
6 who is not vaccinated shall be fined unless they
7 demonstrate proof of immunity or that immunization is
8 not medically appropriate. How do those two
9 sentences not put your client on notice that they
10 were to comply with the resolution irrespective of
11 your argument that the final sentence only refers to
12 the order?

13 MR. SIRI: Because Your Honor, words have
14 meaning. And in the violation description, it has to
15 tell you what you are in violation of. The fact that
16 it has -- I think the fact that it even defines the
17 word resolution further supports why they chose, Your
18 Honor, to say at the end, you are in violation of the
19 order, I don't know.

20 H.O. LEUNG: Okay.

21 MR. SIRI: That's their choice. But that's
22 what they chose to say that my client was in
23 violation of. It did not say my client was in
24 violation of the resolution in this, in this
25 violation description. I think that, I think that if

1 you want to, you know, we are not talking here about
2 giving somebody a little, you know, you are talking
3 here about requiring an injection of a product into,
4 into somebody's body. I think you need to give some
5 very clear and explicit notice of what you are
6 alleging they are violating. I think that if you
7 don't reference the right order of code, section,
8 that's on them. That the least, Your Honor, a
9 minimal safeguard due process, minimal safeguard due
10 process require you to make clear what it is you
11 violated. They said what you've -- they, they, they
12 wrote you violated the order. They chose to do that,
13 you know, that's it. If they wanted to say you
14 violate resolution, they could have done that. It,
15 it shouldn't have to be my client who is not a
16 lawyer, who is not an attorney, who don't know how to
17 speak English that well to try to figure out
18 precisely what it is, you know, they are being
19 claimed they are in violation of. They should be
20 able to read it and say, okay, it says I'm violating
21 the order, period.

22 H.O. LEUNG: Okay. I don't know if you
23 answered my question but I think I -- you did. You
24 are saying that the final sentence because it
25 contains the alleged violation of the order controls

1 because there is no sub -- there's no equivalent
2 allegation. In other words, there's no --
3 respondents failed to vaccinate child CR or otherwise
4 submitted acceptable proof of immunity in violation
5 of the order or resolution which is what you are
6 saying is required if they are going to allege that
7 he violated the resolution. Is that a correct
8 summation of the argument?

9 MR. SIRI: It should say, it should say --

10 H.O. LEUNG: Right.

11 MR. SIRI: Right. It should -- the charge
12 should say, you know, if you look the charging
13 documents, it says in charging documents, criminal
14 court even if it's --

15 H.O. LEUNG: Right.

16 MR. SIRI: This is what you have violated.
17 It should tell you what you vio-, it doesn't say in
18 here anything other than that you've -- that my
19 client has violated the order. It doesn't say in
20 here that it's -- and it say -- it doesn't say in
21 here that they violated the resolution. That's not
22 what it's alleged.

23 H.O. LEUNG: Okay. Anything else from
24 either side?

25 MR. MERRILL: Your Honor, no, it's just

1 that we fundamentally disagree at that. The NOV is
2 only -- to the extent that it put you on notice about
3 the resolution. It does that and it cites 3.05 and
4 that's enough.

5 H.O. LEUNG: Okay. I have enough to make a
6 decision. Is there anything else anyone wants to put
7 on the record before I close the hearing?

8 MR. SIRI: I'm not -- on just that
9 argument, Your Honor. I've got lots of other
10 arguments. That's just the first.

11 H.O. LEUNG: Okay. So, you, you have other
12 things to do?

13 MR. SIRI: Yeah.

14 H.O. LEUNG: Okay.

15 MR. SIRI: That's just the first --

16 H.O. LEUNG: Okay. Okay.

17 MR. SIRI: That's just the first --

18 H.O. LEUNG: Okay.

19 MR. SIRI: -- argument.

20 H.O. LEUNG: Here I was waiting to close
21 the hearing.

22 MR. SIRI: I have got a lot of arguments,
23 oh, no.

24 H.O. LEUNG: Okay. Let's, let's move on to
25 the next argument.

1 MR. SIRI: We are -- okay.

2 H.O. LEUNG: Yeah.

3 MR. SIRI: Were you saying you were going
4 to rule on that argument?

5 H.O. LEUNG: No, no, I don't rule anything.
6 I take things under advisement and I write a
7 decision.

8 MR. SIRI: Okay.

9 H.O. LEUNG: You get a decision in 30 days.

10 MR. SIRI: Okay.

11 H.O. LEUNG: The things that I ruled here
12 today, the only I ruled was your request to have --

13 MR. SIRI: The hearing officer.

14 H.O. LEUNG: -- the hearing -- no, the
15 issuing officer up here.

16 MR. SIRI: The issuing officer.

17 H.O. LEUNG: Because I heard -- obviously
18 if I rule that you are entitled to it, we're going to
19 adjourn the hearing. So, whether or not we have the
20 hearing is determinative on me making that decision,
21 that's why I ruled immediately but everything else,
22 the motions to dismiss, your argument, I'm going to
23 take under advisement and issue a written decision.
24 Since you have many other decisions and we have many
25 other cases, I'm going to ask you, you move along to

1 your next argument.

2 MR. SIRI: Yeah. I, I -- absolutely.

3 Okay. So --

4 [OFF MIC CONVERSATION]

5 MR. SIRI: Okay. So, the second ground,
6 Your Honor, that we move to, to find that this
7 summons was not properly issued is that pursuant to
8 the New York Administrative Code Section 17-148C,
9 okay, it provides that the Board's resolution must be
10 published for three days before the public is deemed
11 to be on notice of the requirements of the
12 resolution.

13 H.O. LEUNG: Okay.

14 MR. SIRI: Okay. If Your Honor would like
15 I can read into the record --

16 H.O. LEUNG: No.

17 MR. SIRI: -- the provision.

18 H.O. LEUNG: I have the provision, you
19 don't, you don't need to read.

20 MR. SIRI: Wonderful.

21 H.O. LEUNG: That's right.

22 MR. SIRI: I'll keep going.

23 H.O. LEUNG: So, you are saying it's failed
24 to do that or prove --

25 MR. SIRI: Right. And, and I'd, I'd like

1 to put in as the -- as -- into evidence. I have --
2 so, I'm, I'm going to be handing Your Honor a copy of
3 the, the City register notice of publication of the
4 resolution.

5 H.O. LEUNG: Okay. I'm going to mark this
6 -- you're -- as Respondent's -- did you put anything
7 else into evidence at all?

8 MR. SIRI: Not yet.

9 H.O. LEUNG: Okay. I'm going to --

10 MR. SIRI: This is the first.

11 H.O. LEUNG: -- mark this as Respondent's
12 1.

13 MR. SIRI: Okay.

14 [OFF MIC CONVERSATION]

15 H.O. LEUNG: Okay. The record should
16 reflect that Respondent's 1 is a print out of the New
17 York City record online report for the Board of
18 Health measles resolution dated 04/17/2019,
19 publication date lists here as 04/22 to 04/24/2019.
20 Any objection to Respondent's 1 coming into evidence?

21 MR. MERRILL: No, Your Honor.

22 H.O. LEUNG: Okay. Department of Health
23 does not object. Respondent's 1 into evidence.
24 Okay. What would you like to comment on Respondent's
25 1?

1 **[Respondent's Exhibit 1 admitted into**
2 **evidence.]**

3 MR. SIRI: Sure. So, the publication, the
4 three days ended on April 24th but yet, the violation
5 was issued on April 21st, that's the date and time of
6 occurrence written on the summons, Your Honor, which
7 means it was issued not even during the three days
8 which in -- which itself wouldn't have been valid.
9 But it was issued even before the three days of
10 notice that was required for publishing the, the,
11 the, the resolution and hence, it was improperly
12 issued.

13 H.O. LEUNG: Counsel for DOH?

14 MR. MERRILL: Just give me a moment, Your
15 Honor. I just want to read on something accordingly.
16 I mean, I think you got to take the -- Your Honor, I
17 think you got to relate two things together that you
18 can't have it that -- not into the fact. So, you
19 know, if, if he is going to say that the Board of
20 Health resolution was in effect, then the order is
21 still in effect [unintelligible] [00:54:51] argue.
22 They can't be -- it can't be that there is this gap.
23 So, it's either one or the other.

24 MR. SIRI: Just two quick things. First,
25 obviously, this is an argument in the alternative,

1 right? In that, I just want to make very clear for
2 the record that our position is the resolution is not
3 alleged of being violated in this order, in -- excuse
4 me, in the summons.

5 H.O. LEUNG: Right.

6 MR. SIRI: So, I am arguing the alternative
7 at the moment that to the extent you found the
8 resolution to actually be in effect and that the
9 resolution, excuse me, was alleged to have been
10 violated in the summons despite not saying that in
11 the summons. It was not effective that, that, that
12 it was improper to have issued this violation on the
13 date of issuance.

14 [CROSSTALK]

15 MR. SIRI: And to respond. No, no, and
16 just --

17 H.O. LEUNG: Okay. Yes.

18 MR. SIRI: And now directly to respond to
19 Mr. Merrill's point, the Board is free to pass a
20 resolution when it did but that doesn't change the
21 notice requirements as we know.

22 H.O. LEUNG: I understand your argument.
23 You are saying that the summons was issued on 04/21
24 and that the notice provided by this publication was
25 first published for three days beginning on April

1 22nd and ending on April 24th and that any summons
2 should have been issued 25th, 26th, 27th. That the
3 fact that it was issued before this was even
4 published is insufficient notice in terms of the --
5 as it pertains to the resolution. I understand your
6 argument and that your position, I understand your
7 position.

8 MR. MERRILL: It would be that the order
9 stays in effect till the, the service was made and,
10 and, and when the resolution becomes effective
11 because there is this requirement and it was put into
12 effect but -- and you can't have it both ways. It's
13 going to be [unintelligible] [00:56:26] one way or
14 the other.

15 MR. SIRI: Mr. Mer-, Merrill may not like
16 the policy result of --

17 H.O. LEUNG: So --

18 MR. SIRI: -- way -- the way the law works
19 but that's what the law provides. It says, any
20 exercise of the Board's power will be effective only
21 until the next meeting of the Board. It was done at
22 the Board meeting. It was over. The fact that there
23 is a gap between the Board meeting, right, and when
24 the notice is done, the vio-, and then they can issue
25 summonses again --

1 H.O. LEUNG: Can I ask a relevant question

2 --

3 MR. SIRI: Yes.

4 H.O. LEUNG: -- because this is what I am
5 going to look at in the hearing.

6 MR. SIRI: Yes.

7 H.O. LEUNG: Assuming that your argument is
8 valid, that the resolution is in effect, not in -- it
9 was a notice, how --

10 MR. SIRI: Yeah.

11 H.O. LEUNG: I'm sorry. How do you deal
12 with the issue of the, the possible issue that
13 petitioner might raise that the Board on the 19th
14 acted to continue the Commissioner's April 9th order
15 and although -- and at -- on April 21st when your
16 client was served with the summons, the order -- I'm
17 not saying it's -- I'm just saying the argument --

18 MR. SIRI: Yeah, I understand.

19 MR. MERRILL: -- the order was in effect.

20 MR. SIRI: There has been no evidence, I
21 assume counsel's, you know, he just -- he's an
22 attorney speaking --

23 H.O. LEUNG: Yeah.

24 MR. SIRI: -- I -- there is no evidence on
25 the record that I am aware of here today so far that

1 shows that the resolution continued the order, right?
2 It's, it's -- the only thing they have pointed to is
3 the resolution language itself, is that correct?

4 H.O. LEUNG: The resolution, --

5 MR. SIRI: Language itself.

6 H.O. LEUNG: -- the summons and the
7 original orders are all the evidence that we have.

8 MR. SIRI: Right. So, so --

9 H.O. LEUNG: And then the respondent's --

10 MR. SIRI: Right. So, nothing --

11 H.O. LEUNG: -- and the testimony.

12 MR. SIRI: Right. I, I have not -- I would
13 love to see the languages, I, I may have read it a
14 few times. I don't see anything in there that says
15 the order is -- of the, of the Commissioner's hereby
16 continue. So, --

17 H.O. LEUNG: Correct, it's not being
18 explicit, right.

19 MR. SIRI: So, there's nothing in there
20 that says --

21 H.O. LEUNG: Yeah.

22 MR. SIRI: So, if -- what you are asking me
23 is -- but if you found it was continued --

24 H.O. LEUNG: Right.

25 MR. SIRI: -- right, could a violation

1 still be issued under the order. And my answer to
2 that is, no, and here is why. I would say it's
3 because what, what takes the place of the order is
4 the resolution, and that's just the way 3.01 is
5 structured.

6 H.O. LEUNG: Mm-hmm.

7 MR. SIRI: It's just, you know, that's --
8 laws are to be enforced the way they are written.
9 And it says that any such exercises of authority
10 shall be effective only until the next meeting of the
11 Board. So, at the next meeting of the Board, that
12 Commissioner's Order became a legal nullity. What
13 took its place is the resolution --

14 H.O. LEUNG: Well, I wanted to say a couple
15 of things.

16 MR. SIRI: Yes.

17 H.O. LEUNG: I, I don't want to
18 [unintelligible] [00:58:46] --

19 MR. SIRI: Sure.

20 H.O. LEUNG: -- because I've done other
21 cases and there are situations where if the Board
22 continues the Commissioner's Order --

23 MR. SIRI: Yes.

24 H.O. LEUNG: -- or finds that it's
25 continued that we then have two live entities at that

1 point. And that's why I'm asking the question.

2 MR. SIRI: Yes.

3 H.O. LEUNG: The live entity being the
4 Commissioner's Order which is extended by the Board
5 and then the Board's resolution. So, you have two
6 live entities at that point. The question that I
7 have is assuming that I, that I find that service was
8 improper as to the resolution, I would like on the
9 record for you to address the other possibility --

10 MR. SIRI: Yes.

11 H.O. LEUNG: -- which is that the
12 resolution extended the order and all the resolution
13 may not be valid because service was not affected in
14 a timely manner as per your argument. How do you
15 address the issue that the order could still be alive
16 at that point by the, by the Board's --

17 MR. SIRI: Right.

18 H.O. LEUNG: -- action?

19 MR. SIRI: To the extent that the order is
20 as you say alive by, by, by operation of the
21 resolution, it's really the resolution that's alive
22 and the order becomes an exhibit to it essentially.
23 The order itself by operation of law -- is gone. It
24 says any such actions of authority of the Board shall
25 be effective only until the next meeting of the

1 Board. So, that Commissioner's Order is a legal
2 nullity.

3 H.O. LEUNG: Okay.

4 MR. SIRI: That the resolution chose to
5 revive it, okay, the resolution chose to do that but
6 it's the resolution that's alive and it's the
7 resolution that then requires notice. What has
8 happened in OATH proceedings before as you know is
9 not binding, you know.

10 H.O. LEUNG: I, I understand.

11 MR. SIRI: But, but, but, which, you know,
12 and, and the fact, and the fact that, you know, the
13 fact that folks have done things --

14 H.O. LEUNG: Right.

15 MR. SIRI: -- certain ways --

16 H.O. LEUNG: I understand --

17 MR. SIRI: -- can't change what the law
18 provides.

19 H.O. LEUNG: And again, the reason why I am
20 saying this is --

21 MR. SIRI: Yes.

22 H.O. LEUNG: -- because when everyone
23 leaves the room and I have to write it, --

24 MR. SIRI: Yes.

25 H.O. LEUNG: -- these are the issues that I

1 have to address. How do you address the, the
2 whereas, second from the -- the third from the bottom
3 on Petitioner's 2 which is the resolution?

4 MR. SIRI: Whereas second from the bottom?

5 H.O. LEUNG: Yeah. Third from the bottom.

6 MR. SIRI: Third from the bottom.

7 H.O. LEUNG: Do you see that?

8 MR. SIRI: Yeah.

9 H.O. LEUNG: Okay. Whereas --

10 MR. SIRI: I, I think that -- whereas
11 pursuant -- I think that actually is precisely --

12 H.O. LEUNG: Right.

13 MR. SIRI: -- it supports the point I have
14 been marking. Whereas pursuant to Health Code
15 section 3.01, the order issued by the Commissioner is
16 only in effect until the Board of Health convenes it
17 and either continues or rescinds the Commissioner's
18 exercise of authority. Even the Board made it clear
19 and understood what happens to the order. It needs
20 to be either continued or rescinded, right?

21 H.O. LEUNG: Right.

22 MR. SIRI: And in it, it does -- it still
23 doesn't say in here.

24 H.O. LEUNG: So, what do you say happened -
25 - what did the resolution do to the order in your

1 opinion?

2 MR. SIRI: The -- in my opinion, what the
3 resolution does is it doesn't rescind it and it
4 doesn't continue it.

5 H.O. LEUNG: Okay. I understand your
6 argument.

7 MR. SIRI: But for the purposes of this
8 argument that I'm making about notice, I actually
9 don't think that matters.

10 H.O. LEUNG: Right.

11 MR. SIRI: Does it?

12 H.O. LEUNG: The notice matters to the
13 resolution. I'm talking about the order. So, my
14 question to you is, your position is that the
15 resolution doesn't address continuing or --

16 MR. SIRI: It doesn't con-, continuing --

17 H.O. LEUNG: Or rescinds --

18 MR. SIRI: -- or rescinding.

19 H.O. LEUNG: -- Commissioner's Order, is
20 that correct?

21 MR. SIRI: Right. That's right. But even
22 if it -- it, it doesn't.

23 H.O. LEUNG: Right.

24 MR. SIRI: But even if it did, it would be
25 basically reviving the Commissioner's Order --

1 H.O. LEUNG: Right.

2 MR. SIRI: -- as through the resolution.

3 H.O. LEUNG: We've been talking a lot. I'm
4 going to give Department of Health --

5 MR. SIRI: Yeah, yeah.

6 H.O. LEUNG: -- an opportunity. Counsel
7 for Department of Health, do you want to address some
8 of the issues that I have been asking?

9 MR. MERRILL: I think -- yeah, I think we
10 have to go back and if you remember that this was an
11 emergency that the Commissioner [unintelligible]
12 [01:02:12] you know, acted appropriately. The Board
13 did continue the requirement that, that people be
14 vaccinated. The only thing the words change, yes or
15 no, you know, whatever, but you can -- it cannot be
16 and I think, you know, again, when the -- this is a
17 remedial action too. The re-, that requirement had
18 to still be in effect. It had to be in effect until
19 the Board, the resolution was in effect.

20 H.O. LEUNG: What, what is, what is your
21 position, counsel for DOH regarding what the reso-,
22 what the board did in its resolution vis-à-vis the
23 Commissioner's Order? Did it rescind it, did it
24 continue or did it not do -- address it in anyway?

25 MR. MERRILL: It doesn't, it doesn't -- it,

1 it continued the basic requirement that people be
2 immunized until, until this becomes effective and
3 take over. And then this became the document but --
4 so -- but I would argue that the effective date of
5 that in question has to be the date that it's served.
6 And that until then and all they are charged in the
7 NOV, there was a requirement under both that people
8 be immunized and this woman was not immunized. She
9 continues not to be immunized and the child continues
10 not to be immunized in violation of the order.

11 MR. SIRI: I would object to hearsay but
12 obviously you said that's not appropriate.

13 H.O. LEUNG: Yeah, hearsay is permitted.

14 MR. SIRI: Can I please --

15 MR. MERRILL: But we should -- we could
16 save a lot of time --

17 H.O. LEUNG: Counsel --

18 MR. SIRI: Go ahead.

19 MR. MERRILL: Okay.

20 H.O. LEUNG: What is your position, Mr.
21 Merrill as to whether or not on April 21st when the
22 summons was issued as to whether or not the
23 Commissioner's Order P1 was, was or was not in
24 effect?

25 MR. MERRILL: I, I, I think that the -- I

1 think that, that the -- at that time, the resolution
2 was in effect. That the resolution, it says that it
3 took effect immediately, if you look at the last
4 sentence.

5 H.O. LEUNG: Okay.

6 MR. MERRILL: And, and I would go again, I
7 would -- if, if -- so if you are going to say that
8 the service was short because it was before the, the
9 third publication, then I think it's a service issue.

10 H.O. LEUNG: Right.

11 MR. MERRILL: But I do, I do believe
12 looking at the terms of the, the resolution it says
13 that it took effect immediately.

14 H.O. LEUNG: Okay. Alright. Is there
15 anything -- do you have any other arguments because
16 you said you had a whole bunch, so I --

17 MR. SIRI: Yeah. Yes.

18 H.O. LEUNG: Okay. Go ahead.

19 MR. SIRI: Okay. Third --

20 [OFF MIC CONVERSATION]

21 MR. SIRI: Your Honor, may I, may I just
22 put on the record constitutional arguments of just
23 personally, I will just say that --

24 H.O. LEUNG: Absolutely.

25 MR. SIRI: -- to preserve them for appeal -

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H.O. LEUNG: Sure.

MR. SIRI: -- as I understand you can't rule on them.

H.O. LEUNG: Yeah.

MR. SIRI: Okay.

H.O. LEUNG: You can put any, any one on the record.

MR. SIRI: I'm going to -- I, I -- and I, and I -- to, to be judi-, to be efficient, I would just -- I would not argue them. I will simply state what violations I believe had occurred.

H.O. LEUNG: Okay.

MR. SIRI: Okay. And so, you know, I understand the tribunal can't adjudicate constitution -- constitutional issues but I want to preserve the record that holding respondents in violation for simply existing in their homes, in the state that God created them and issuing them a violation for not injecting a product to their children against an uninformed decision violates the constitutional rights to inform consent under the New York State Constitution and U.S. Constitution, parental choice under the New York State Constitution and U.S. Constitution, bodily integrity under the New York

1 State and U.S. Constitution, free exercise of
2 religion under the New York State and U.S.
3 Constitution, substantive due process to life and
4 liberty under the New York State and U.S.
5 Constitution, procedural due process under the New
6 York State and United States Constitution, the Ninth
7 Amendment right under the United States Constitution
8 and the cruel and unusual punishment under the New
9 York State and United States Constitution. And I, I
10 would also add that the, you know, the, the
11 Commissioner's Order and resolution to the effect --
12 statute find it effective and the summons are also in
13 access of jurisdiction, we believe error of law,
14 arbitrating capricious and abuse of discretion, and
15 abuse of discretion as to the measure and, and mode
16 of the penalty. And I would like to just preserve
17 those for the record, Your Honor. I would also ask
18 that in order for me to properly address most of
19 those arguments, I would need to conduct discovery
20 and, and because of that, I, I am going to make an
21 application to depose the Commissioner of the New
22 York City Department of Health who issued the
23 resolution as well as the -- to the extent that if
24 Your Honor found that the resolution was effective, I
25 would also seek to depose the, the representative of

1 the Board of Health.

2 H.O. LEUNG: We have representatives for
3 the Board of Health here. Which, which
4 representative --

5 MR. SIRI: The, the actual -- the, the head
6 of the Board of Health. I would seek to depose both
7 of those individuals.

8 H.O. LEUNG: The Commissioner of the
9 Department of Health?

10 MR. SIRI: The Commissioner of the
11 Department of Health. Is that the person who is the
12 head of Board of Health?

13 MR. MERRILL: She is the chair.

14 MR. SIRI: Thank you very much. Then I
15 would seek to just depose the Commissioner of the
16 Department of Health.

17 H.O. LEUNG: Okay. Can you just summarize
18 --

19 MR. SIRI: Yes.

20 H.O. LEUNG: -- your basis for your
21 discovery request?

22 MR. SIRI: Sure, Your Honor. The, the, the
23 basis for the application is that in order to make a
24 fulsome record as to the violations of, of the New
25 York State Constitution and U.S. Constitution as well

1 as to various other provisions of law including CPLR,
2 it's Article 78 of the, of the CPLR having a fulsome
3 record as to the factual basis upon which the
4 Commissioner decided, every single sentence in the
5 resolution and the order is necessary. I could -- I
6 don't want to belabor it but there are lots of
7 representations in the order. For example, that
8 measles -- with regards to measles, with regards to
9 the MMR, with regards to the safety and efficacy of
10 that product, as well as with regards to the concerns
11 regarding the measles virus. And, and those underpin
12 the ultimate order in here and I think that the
13 Commissioner should have to answer to, you know, be
14 able to be put to the proof of her claims in this
15 order. To -- in order to actually address those
16 constitutional and, and other grounds which I
17 understand you can't adjudicate at this level. I
18 would also --

19 H.O. LEUNG: Before, before you move on --

20 MR. SIRI: Yes, please.

21 H.O. LEUNG: I want to just put on the
22 record for that, we have a physician here who is a
23 representative of the Department of Health who can
24 address those underpinning questions that you have.
25 So, again, I'm going to ask you what is it about the

1 Commissioner herself that you would like to ask that
2 cannot be answered by the physician here regarding
3 those specific questions that you just addressed.

4 MR. SIRI: Well, Commissioner issued the
5 order, Your Honor.

6 H.O. LEUNG: I understand that, but we have
7 representatives of the Commissioner here who are
8 standing in for her in terms of representing them
9 here.

10 MR. SIRI: And they speak on her behalf?

11 H.O. LEUNG: They are representative of the
12 Department just like district attorneys represented
13 by assistant district attorneys, --

14 MR. SIRI: Alright.

15 H.O. LEUNG: -- general counsels are here
16 for them.

17 MR. SIRI: Right. So, as you know, when,
18 you know, you bring those cases, you bring them
19 against the actual Commissioner and their capacity
20 obviously as the Commissioner of the department but
21 against the Commissioner themselves. And so, I'm
22 asking are they speaking on behalf of the
23 Commissioner here today?

24 H.O. LEUNG: I'm going to -- you can ask
25 them the question. How do you want to address this?

1 MR. MERRILL: Well, I'm not sure what he --
2 in terms of what he is asking. I'm, I'm having a
3 hard time understanding how -- I think this is really
4 just on the [unintelligible] [01:10:19] ploy because
5 I am having a hard time understanding --

6 MR. SIRI: I object to that.

7 MR. MERRILL: Well, but, but hear me out,
8 Mr. Siri.

9 MR. SIRI: That's okay, but --

10 MR. MERRILL: Because I, I have a hard time
11 understanding how a deposition is relevant, you know,
12 if you believe this is unconstitutional which by the
13 way the courts haven't agreed with that decision,
14 then okay, you know, you could -- you should be able
15 to articulate how un-, unconstitutional regardless of
16 deposing the Commissioner on, on what she believes
17 and science believes on, on measles and, and the
18 efficacy of the vir-, of the, the MMR. And we should
19 point out there was litigation challenging the order,
20 it was upheld. So, the constitutional arguments were
21 rejected in terms of the free exercise that was
22 rejected in Prince [phonetic] versus City of New
23 York. It was again more recently objected --
24 rejected in the unsuccessful challenge to the New
25 York State elimination of a religious exemption to

1 vaccine. So, again, you can put on the record that
2 you believe all of these things are unconstitutional.
3 You can -- but not everyone is going to agree with
4 you and a lot of courts haven't but they come out and
5 say, well, I need to depose the plan -- you know, and
6 ask a whole bunch of questions on, on, on the
7 medicine on why you believe measles are bad and why
8 you believe the MMR is safe. I don't think -- I, I
9 have a really hard time understanding how it goes to
10 those constitutional arguments.

11 MR. SIRI: So, the only persons I heard
12 address was on the free exercise, not the -- all of
13 the grounds that I raised. That's one and second --

14 MR. MERRILL: I --

15 H.O. LEUNG: -- I am not here to response
16 to your question, Your Honor, whether or not they are
17 here speaking on behalf of the Commissioner who
18 actually issued the order.

19 H.O. LEUNG: Okay. I think that's like a
20 hyper technical question. They are a representative
21 of the agency which the Commissioner is the head of.
22 So, you are saying, do they directly represent and
23 speak for the Commissioner? I mean, that's -- I, I
24 don't know if, I don't know if you want to ask --

25 MR. MERRILL: I mean, if he wants to, like

1 so again, I'm not sure. I'm probably picking a poke
2 here because I don't know what he wants to ask. If
3 he wants to ask our position on measles and vaccine,
4 Dr. Rosen clearly, I think, can testify about that
5 and speak for the, you know, the agency and that you
6 know, --

7 H.O. LEUNG: So, Counsel, based upon your
8 record and you may have more basis of your reason for
9 deposing the Commissioner, I'm going to deny you
10 because I believe that this doctor here can answer
11 those questions. I'm going to give you a full
12 opportunity to start if you want to ask the doctor
13 questions, please do.

14 MR. SIRI: Okay. I will get to those.
15 I've got few, just few more quick procedural things,
16 Your Honor, beforehand.

17 H.O. LEUNG: Okay.

18 MR. SIRI: And we'll, we will get to that.

19 [OFF MIC CONVERSATION]

20 H.O. LEUNG: Okay. Go ahead, Counsel.

21 MR. SIRI: Okay. Okay.

22 **CROSS EXAMINATION OF DR. ROSEN**

23 **BY MR. SIRI**

24 Q: I'm sorry, doc -- was it Doctor --

25 A: Rosen.

1 Q: Dr. Rosen, alright. Good morning. I'm going to
2 ask you few questions, Dr. Rosen. If you don't understand
3 any of the questions at any time, please let me know,
4 okay? Sorry?

5 A: Yes.

6 Q: Okay.

7 MR. SIRI: And, and the witness was sworn
8 in?

9 H.O. LEUNG: Yes, she was.

10 MR. SIRI: Okay.

11 Q: And you understand you are testifying under
12 penalty of perjury, correct?

13 A: Correct.

14 Q: Okay. In order to streamline some of my
15 questions, I'm going to just read you a list of acronyms
16 and if you can tell me what they mean, this way, we have
17 defined terms as we go through some questioning relating
18 to the order. HHS, do you -- what does that stand for, if
19 you know?

20 A: Health and Human Services.

21 Q: Yeah. The, the department of Health and Human
22 Services. And, and CDC?

23 A: Centers for Disease Control and Prevention.

24 Q: And prevention, correct?

25 A: Yes.

1 Q: Okay. Have you ever worked for the CDC or have
2 been involved with the CDC?

3 A: I have.

4 Q: Okay. When did you work for the CDC?

5 A: From 2007 through 2009.

6 Q: And what, what did you do there?

7 A: I served as an Epidemic Intelligence Service
8 Officer.

9 Q: And you are aware that HHS is the department
10 under which the CDC -- is an agency under the Department
11 of HHS, correct?

12 A: Correct.

13 Q: Okay. And what does the FDA stand for?

14 A: Food and Drug Administration.

15 Q: Okay. And, and ACIP?

16 A: Advisory Committee on Immunization Practices.

17 Q: And that is a community within the CDC, correct?

18 A: Correct.

19 Q: Okay. And they are the ones who essentially are
20 the -- is the board that decides the CDC's vaccination
21 schedule that most physicians in the country follow,
22 correct?

23 A: They make the national recommendations for the
24 routine immunization program.

25 Q: So, when you pull up the CDC immunization

1 schedule, that's the schedule that ACIP has voted upon
2 essentially?

3 A: With the ACIP recommendations.

4 Q: Yeah. And, and the IOM?

5 A: That's the Institute of Medicine.

6 Q: And that's part of the National Academy of
7 Sciences, correct? And that is not part of HHS unlike the
8 CDC and FDA, correct?

9 A: Correct.

10 Q: That they are an independent body?

11 A: Correct.

12 Q: They are hired to conduct science and scientific
13 reviews, right?

14 A: I can't speak to the process for hiring.

15 Q: Okay. As the CD -- okay, fair enough. Have you
16 worked for any other federal health agencies other than
17 the CDC?

18 A: No.

19 Q: Okay.

20 A: I was with the Commissioned Corps.

21 Q: With the what, I'm sorry?

22 A: I was an employee of the Commissioned Corps when
23 I was based at the CDC.

24 Q: Okay.

25 A: The U.S. Public Health Service.

1 Q: Great. So, so, you got to wear the regalia?

2 Okay.

3 A: I did.

4 Q: Are you familiar with the National Childhood
5 Vaccine Injury Act of 1986?

6 A: Not very familiar.

7 Q: But are, are you at least aware that it is the
8 Act that gave immunity to liability to pharmaceutical
9 companies for injuries caused by their vaccine products?

10 A: I don't know the details.

11 Q: But I'm asking for your -- what your knowledge
12 is. Are you aware whether or not pharmaceutical companies
13 can be sued for injuries caused by their vaccine products?

14 A: I am not aware of it.

15 Q: You don't know?

16 A: No.

17 Q: Okay. So, what do you know about the National
18 Childhood Vaccine Injury Act of 1986?

19 A: I -- that's -- I don't know. I mean, I rarely
20 [unintelligible] [01:17:16] that act.

21 Q: Nothing at all? So, you are not aware that the
22 manufacturer of the MMR vaccine, Merck, cannot be sued for
23 injuries caused by their MMR vaccine?

24 A: I am not familiar with the process for
25 manufacturing companies.

1 Q: Are you aware -- but are you, are you aware that
2 -- you can answer yes or no on that one, I would pre-, --
3 are you, are you --

4 A: No, I'm not aware.

5 Q: You are not aware of that? So, you are not aware
6 that Merck can be sued for injuries caused by the MMR
7 vaccine?

8 A: No.

9 Q: Okay. What's a virus?

10 A: A virus is a -- it's an infectious disease
11 particle that can lead to an illness, of which measles is
12 one example.

13 Q: Okay. How does it lead to illness?

14 A: It enters a person's body through different
15 possible routes. It could be respiratory, it could be
16 through the blood. And it can replicate and it can cause
17 -- it can in-, infect different organs of the body and
18 cause symptoms.

19 Q: Alright. Viruses replicate and they take over
20 the cell, cells in the body either they are going to DNA
21 or they [unintelligible] [01:18:40] fluids, right?

22 A: Correct.

23 Q: And then they can -- the, the cells, okay.
24 Alright. So, and, and usually, the route of infection is
25 actually on the costal surfaces, right, your eyes, your

1 intestinal tract, your lungs, that's the normal route that
2 you would -- a human being would be contact with the
3 virus, correct?

4 A: That's a common route, yes.

5 Q: Okay. Did you discuss your appearance or
6 testimony here today with anybody before today, before,
7 before this hearing started?

8 A: Yes, at work, it was discussed that I would be
9 attending here.

10 Q: Okay. Who did you discuss that with?

11 A: The people that are in the room.

12 Q: Other than your conversations with counsel,
13 anybody that wasn't an attorney?

14 H.O. LEUNG: I'm, I'm going to just put on
15 the record this is the Hearing Officer speaking. Mr.
16 Siri, what I'm going to do is, I'm going to allow you
17 ask a relevant questions and I understand --

18 MR. SIRI: I'm just, I'm just getting a
19 foundation going.

20 H.O. LEUNG: I understand that.

21 MR. SIRI: And it's taking long.

22 H.O. LEUNG: The reason why I'm, I'm, I'm
23 cutting this short and I ask you to cut it short is I
24 want you to get to the issues regarding the policy.
25 I think you had some policy issues. I don't want

1 this to be a mid-round. I, I know you asked for a
2 deposition of the Commissioner and you asked whether
3 or not [unintelligible] [01:20:00] spoke to the
4 Commissioner. So, what I'm going to do is just limit
5 your questions to relevancy as to what we are here
6 for which is a hearing. We have nine other cases. I
7 understand you have to -- I'm giving you a lot of
8 leeway. Normally, I don't have hearings that last an
9 hour. We don't have that time but I'm giving you of
10 a lot of leeway to ask the doctor relevant questions.
11 Who she spoke to in preparation for this, I don't
12 believe is relevant. If you are going to challenge
13 her credibility, you can do it with questions
14 regarding her, her knowledge about the medical
15 science and things of that nature. It's not a full
16 on trial. In other words, I don't -- we don't have
17 the resource and the time for that. So, I'm going to
18 ask you to just get to the relevant questions.

19 MR. SIRI: Okay. Can I ask her about her
20 background?

21 H.O. LEUNG: You can.

22 MR. SIRI: Okay.

23 H.O. LEUNG: Yeah.

24 Q: Can you tell us about just very tersely what --
25 what's your education? What degrees you hold?

1 A: I have a Bachelor in Science from Cornell
2 University, an MD from Stony Brook Medical Center.

3 Q: Mm-hmm.

4 A: I completed a residency in internal medicine at
5 NYU. I completed a fellowship at the CDC as an Epidemic
6 Intelligent Service Officer where I worked with
7 respiratory diseases branch. I have been at the New York
8 City Department of Health since 2009.

9 Q: Okay.

10 A: I'm currently the Director of Epidemiology and
11 Surveillance for the Bureau of Immunization where I
12 oversee surveillance and operate investigations for
13 vaccine, preventable diseases including measles.

14 Q: Okay. Thank you. Now, in the summons, it states
15 that, a review of the department records show that
16 respondent who is at least six months old lives at --
17 provides an address which is located in one of the
18 effected zip codes. How did the department determine the
19 respondent's address?

20 A: This person was exposed to -- identified as
21 having been exposed to measles. And when an exposure
22 occurs, so for example, if somebody is exposed at a
23 medical facility, the address, the name and the address of
24 the people exposed are provided to the Health Department.
25 So --

1 Q: By the physician's office?

2 A: By the place where the exposure occurred. So,
3 for example, if it was -- the exposure occurred at an
4 outpatient medical provider's office, the address would
5 have been provided by that provider.

6 Q: Okay. And so, who was providing with these names
7 and address? Was it medical providers typically?

8 A: A majority of the exposures that occurred did
9 happen in medical settings and so it was the healthcare
10 facility that would have --

11 H.O. LEUNG: Can we just limit the
12 questions as to this particular child and not policy
13 as to this child. Doctor, --

14 MR. SIRI: Sure.

15 H.O. LEUNG: -- do you know how --

16 MR. SIRI: Yeah.

17 H.O. LEUNG: -- the Department of Health
18 came in possession of his -- this address?

19 DR. ROSEN: I don't know the details of
20 where this particular person was exposed.

21 H.O. LEUNG: Okay. Counsel, next question.

22 Q: But how did you get the address, from who?

23 A: As I mentioned, I don't know for this particular
24 child where they were exposed to have acquired the list of
25 people exposed. So if, if they were exposed in a

1 healthcare facility, it would have been the healthcare
2 facility.

3 Q: But you don't know the name of the healthcare
4 facility that provided that information?

5 A: We could obtain that, I do not have that.

6 Q: And you, and you don't know -- and, and you just
7 know that -- you believe that the address came from that
8 unknown facility, unnamed facility?

9 A: An address would have been provided at -- by the
10 setting of exposure. I don't know if it was a medical
11 facility but if, for example, it were, that's where we
12 would have received the initial address. We also have
13 access to the Citywide, the New York City, Citywide
14 Immunization Registry which -- in which providers are
15 required to enter vaccination records to all -- for all --
16 for doses administered to all children in New York City.
17 That's another source of address information.

18 Q: And that registry, does it sometimes have -- is
19 it sometimes missing immunizations that have been
20 administered?

21 A: The vast majority because it's required by law
22 for providers in New York City to adminis-, to enter doses
23 that were administered, it is highly complete. It's not
24 100 percent complete. And so, typically in the setting of
25 an exposure to measles when people are identified as

1 having been exposed, if we identify a child who doesn't
2 have documentation of vaccination, if they had been
3 exposed in a healthcare facility, we would typically reach
4 out to the healthcare facility and ask if they have any
5 supplemental records that hadn't been entered into the
6 CIR. We would also try contacting -- we, we may try
7 contacting the family of the person who is exposed and
8 request additional information.

9 Q: But you don't know the name of the health
10 facility for this respondent, correct?

11 A: I do not know where this --

12 Q: So, you don't know --

13 A: -- particular person was exposed.

14 Q: And, and so you are, you are assuming that that
15 happened in this instance. You don't know for sure,
16 correct?

17 A: I know -- I'm assuming what?

18 Q: You, you are assuming that the procedure you just
19 outlined for confirming records happened in this instance
20 but you don't know?

21 A: I don't know where this person was exposed. I do
22 know that for every person who is exposed to measles and
23 who received a summons, before someone receives the
24 summons, they are looked up in the Citywide Immunization
25 Registry.

1 Q: And who did that in this instance?

2 A: One of the staff at the Health Department.

3 Q: Okay. You didn't do it?

4 A: No.

5 Q: What's the name of the respondent in this case?

6 MS. PEONE: The, the respondent or the
7 child?

8 MR. SIRI: The respondent. I see --

9 DR. ROSEN: Malky Tabak.

10 MR. SIRI: -- we are not charging the
11 child.

12 Q: What's that?

13 A: Malky Tabak.

14 Q: Okay. And what's the name of their child or her
15 child?

16 MS. PEONE: Give him by going by only
17 initials.

18 H.O. LEUNG: I'm going to not allow that
19 for the privacy reasons, we only use the initials.

20 Q: Let me ask this. Do you know the name of the
21 child?

22 A: I do not.

23 Q: Okay. Do you know whether the respondent's child
24 had moderate or severe acute illness with or without the
25 record date and time the summons -- of the violation

1 listed on the summons?

2 A: I know that we do not have documentation of any
3 contraindication to rec-, to having been vaccinated.

4 Q: Please answer my question. Do you know whether
5 respondent's child had moderate or severe acute illness
6 with or without fever at the date and time the violation
7 listed on the summons?

8 A: I do not. I --

9 Q: Do you know whether respondent's child had a
10 severe allergic reaction after a previous dose of any
11 vaccine?

12 A: We don't have any documentation of such a
13 reaction.

14 Q: Okay. Please answer the question. Do you know
15 whether or not respondent's child had a severe allergic
16 reaction after a previous dose of any vaccine?

17 A: No.

18 Q: Do you know whether respondent's child had a
19 severe allergic reaction after previous dose of any other
20 drug?

21 A: We don't have any such documentation.

22 Q: Okay. Well, I'll ask you again. Do you know
23 whether respondent's child had a severe allergic reaction
24 after previous dose of any other drug?

25 A: No.

1 Q: Okay. Do you know whether respondent's child had
2 a severe allergic reaction in the past to a vaccine
3 component?

4 A: We don't have such documentation.

5 Q: Yes or no, please.

6 A: No.

7 Q: Do you know whether respondent's child was
8 allergic to gelatin?

9 A: We don't have such documentation. I'm not aware
10 for this child, no.

11 Q: Are you aware whether the child is allergic to
12 gelatin?

13 A: No.

14 Q: Do you know whether the child is allergic to
15 chicken embryo cells?

16 A: No.

17 Q: Do you know whether the child's -- the
18 respondent's child is allergic to human diploid lung
19 fibroblast?

20 A: No.

21 Q: Do you know whether the respondent's child is
22 allergic to fetal bovine serum?

23 A: No.

24 Q: Do you know whether the child is allergic to
25 neomycin?

1 A: No.

2 Q: Do you know whether the respondent's child is
3 allergic to sorbitol?

4 A: No.

5 Q: Do you know whether the respondent's child has
6 severe immunodeficiency or any kind of immunodeficiency?

7 A: No.

8 Q: Do you know whether respondent's child has a
9 family history of altered immunocompetence?

10 A: No.

11 Q: Are you aware of whether the child --
12 respondent's child has received within the last 11 months
13 any antibiotic containing blood products?

14 A: No.

15 Q: Are you aware whether respondent's child has a
16 history of thrombocytopenia?

17 A: No.

18 Q: Are you aware whether child -- respondent's child
19 has a history of thrombocytopenia purpura?

20 A: No.

21 Q: Are you aware that all the items just listed are
22 some of the contraindications to the MMR vaccine listed by
23 the CDC and adopted by the New York City Department of
24 Health?

25 A: Some are, correct.

1 Q: Which ones aren't?

2 A: So, you did, you did list contraindications to
3 vaccination, several of the ingredients that you listed to
4 the vaccine would not cause an allergic reaction.

5 Q: And --

6 A: I think, I think your point was to say that a
7 contraindication would be a severe allergic reaction to a
8 vaccine or a component and that's correct.

9 Q: So, you are saying that having an -- you are
10 saying that it's not a contraindication to be allergic to
11 some of the ingredients in the vaccine that I have just
12 listed?

13 A: I'm saying that it is a contraindication if you
14 are allergic to a vaccine component. I am saying that
15 allergic reactions are not expected to all of the
16 ingredients that you listed.

17 Q: And how do you know that?

18 A: Because we know what common allergies are.

19 Q: When you say we, who do you mean?

20 A: Common al-, common allergies would be to
21 something or an allergic reaction could occur typically to
22 something like neomycin or gelatin.

23 Q: And those are contained in the MMR vaccine?

24 A: Correct.

25 Q: But you don't know whether this child has an

1 allergy to those, correct?

2 A: I know that this family did not submit medical
3 documentation.

4 Q: Do you know whether this child has an allergic
5 reaction to gelatin or neomycin before this summons was
6 issued?

7 A: I do not.

8 Q: Okay. Now, your violation is based on
9 respondents not providing the MMR vaccine to the child,
10 correct?

11 A: Correct. And not --

12 Q: Okay.

13 A: -- and not submitting documentation of immunity
14 or a medical contraindication.

15 Q: Does the benefit outweigh the risk for injecting
16 MMR vaccine into, into this child?

17 A: Based on the information we have, yes.

18 Q: But you don't know whether or not this child has
19 any of the contraindications we just listed, correct?

20 A: Well, that the -- they were notified that they --
21 if there were medical contraindication that that
22 documentation should be submitted.

23 Q: Before the summons was issued, did the Health
24 Department know whether this child had any of the
25 contraindications we just went through?

1 A: No, and that's why the family was giving -- given
2 an opportunity to submit that documentation.

3 Q: So, when this summons was issued and sitting here
4 today, you don't know whether or not the child has a
5 contraindication to any -- to the MMR vaccine, correct?

6 A: Correct.

7 Q: Okay. So, I'm going to ask you again, sitting
8 here today, do you know whether the benefits of the MMR
9 vaccine outweigh the risk for this child?

10 A: Based on the information that we currently have
11 received, yes.

12 H.O. LEUNG: Sir, I'm going to ask you to
13 move on to a different subject. You've retraced --

14 MR. SIRI: Okay.

15 H.O. LEUNG: -- and retraced so --

16 MR. SIRI: Yeah.

17 H.O. LEUNG: So, Mr. Siri, go ahead now.

18 Q: Did you contact the respondent to ask if their
19 child had received the MMR vaccine?

20 A: I cannot comment on this particular case.

21 Q: You don't know? I'm asking for your knowledge.

22 You are here testifying --

23 A: Yes, I know that we do not have any documentation
24 of vaccination or a medical --

25 Q: I'm asking, did you contact the respondent to ask

1 if their child had received the MMR vaccine?

2 A: I did not.

3 Q: Okay. Do you know -- do you have specific
4 knowledge of somebody at the Health Department contacting
5 the respondent to ask if the child had received the MMR
6 vaccine?

7 A: I, I don't have access to that information right
8 now. It's possible that someone from the Health
9 Department called the family.

10 Q: Okay. But you don't know?

11 A: We can --

12 Q: Do --

13 A: -- we can confirm that. I do not have that --

14 Q: I'm asking, but you don't know, right?

15 A: I do not know.

16 Q: Okay. Did anybody from the Health Department
17 contact this respondent to ask if their child has a
18 contraindication to the MMR vaccine?

19 H.O. LEUNG: To -- let me just say this.
20 Doctor, to the best -- to your own personal
21 knowledge, you can't speak for anyone else or any
22 other, just to your own personal knowledge, answer
23 that question. I'm going to ask to take a break.
24 Just give me two seconds here. I'm going to pause
25 the hearing for a second.

1 [OFF THE RECORD]

2 [ON THE RECORD]

3 H.O. LEUNG: Okay. The record should
4 reflect, I stepped out, spoke to a hearing
5 supervisor, I'm back in. Go ahead, counsel.

6 MR. SIRI: Okay. Thank you.

7 Q: Doctor?

8 A: Yes.

9 Q: Does, does the MMR vaccine involve an injection
10 into the body?

11 A: I, I would like to go back to your question about
12 --

13 Q: Well, your, your, your, your attorn-, your --

14 MR. MERRILL: Yeah.

15 MR. SIRI: -- yeah, when I'm done, you can
16 redirect.

17 H.O. LEUNG: Two things, Counsel.

18 MR. SIRI: Yeah.

19 H.O. LEUNG: I, I don't mean to cut you
20 short.

21 MR. SIRI: Yeah.

22 H.O. LEUNG: We have nine other hearings.

23 MR. SIRI: Yeah.

24 H.O. LEUNG: I'm going to ask you, is your
25 overall argument here in, in, in this line of

1 questioning, is that it wasn't medically necessary
2 for this child or it was --

3 MR. SIRI: It's -- that's one of the
4 reasons under the order is, is, is that --

5 H.O. LEUNG: Right.

6 MR. SIRI: -- whether it was medically
7 appropriate or not, I seek to establish here today,
8 yes. But I need the opportunity to establish a
9 factual record, Your Honor. Without establishing it,
10 I don't know how you could rule on, on that point.

11 H.O. LEUNG: Okay. Because normally, you
12 establish that record by bringing in evidence. In
13 other words --

14 MR. SIRI: You want to put the burden on my
15 client?

16 H.O. LEUNG: No, no, no, I'm not putting
17 the burden but the issue is that you were served a
18 summons that said there was no proof of immunization
19 or proof of immunity or proof of a medically -- a
20 medical exemption. So, those are the three
21 allegations here. No immunization, no proof of
22 immunity and no --

23 MR. SIRI: It just -- it doesn't say
24 anything about a medical exemption. It -- in the, in
25 the violation, in the, you know, the last sentence.

1 But, but even if, but even if, even if it did, I, I
2 certainly should have the opportunity to present the
3 defense that it wasn't medically appropriate, how
4 could I not?

5 H.O. LEUNG: No, no, you can present a
6 defense. All I am saying is that, if you ask her
7 questions and she says -- you know what, I'm going to
8 go, I'm going to let you continue, go ahead.

9 MR. SIRI: Thank you, Your Honor.

10 Q: So, does the MMR vaccine involve an injection
11 into the body?

12 A: Yes.

13 Q: Okay. What company manufactures the MMR vaccine
14 used in the United States?

15 H.O. LEUNG: Okay. That's what I'm talking
16 about. I mean, how is that relevant to the hearing
17 that I am doing?

18 MR. SIRI: They are involved -- they are,
19 they are ordering in -- she, she testified they order
20 the injection of this product into my client's body.
21 You don't think in understanding that product, its
22 risks, its benefits is relevant to whether it's
23 medically appropriate to require that injection?

24 H.O. LEUNG: Well, it can be appropriate.
25 The issue right now is whether or not -- I understand

1 your overall argument in terms of the constitutional
2 arguments and I think --

3 MR. SIRI: No, no, not only the
4 constitutional argument.

5 H.O. LEUNG: Yeah.

6 MR. SIRI: The order provides it should be
7 medically appropriate, right. And so, I, I am
8 seeking to establish it was medically appropriate.

9 H.O. LEUNG: And -- okay. Let me just take
10 a look real quick at what the order says, because
11 what's going to happen here is --

12 MR. SIRI: So, you are saying there is no,
13 there is no medical exemption in this order. You are
14 saying, this child has to get it no matter what?

15 H.O. LEUNG: No, no, no, I'm saying that
16 you are served with this summons and that they are -
17 the, the --

18 MR. SIRI: I understand.

19 H.O. LEUNG: The summons established --

20 MR. SIRI: I understand.

21 H.O. LEUNG: -- that -- okay. The, the
22 summons established a prima facie case against your
23 client that they didn't get immunized as ordered by
24 the Commissioner or in the alternative, show proper
25 immunity to the measles or a proper medical

1 exemption. We are here for that hearing now.

2 MR. SIRI: Okay.

3 H.O. LEUNG: The summons alleges that. So,
4 they are saying that they don't -- that your client
5 didn't do any of those three alleged things and that
6 you're getting immunized, show proof of immunity or
7 proof of --

8 MR. SIRI: Even if I accept, even if I
9 accept everything you just said Your Honor, which I,
10 I --

11 H.O. LEUNG: No, it's an allegation. I'm
12 not saying you accept that.

13 MR. SIRI: Right, but if, but if --

14 H.O. LEUNG: I'm saying that's what the
15 summons alleges.

16 MR. SIRI: Well, if the summons does allege
17 that, though I will say it says failed to vaccinate
18 or provide proof of immunity but let's just say it
19 also failed to provide, you know, medically, that
20 it's not medically appropriate which it doesn't say
21 that in the last sentence.

22 H.O. LEUNG: Okay, alright.

23 MR. SIRI: This -- I'm, I'm seeking to
24 establish that right now.

25 H.O. LEUNG: Establish what?

1 MR. SIRI: That it's not medically
2 appropriate.

3 H.O. LEUNG: Medical exemption --

4 MR. SIRI: Well, you're, you are using, you
5 are using this for medical exemption. Well, it says
6 medically appropriate.

7 H.O. LEUNG: Okay. What I'm going to do
8 is, you're, you're making the argument that it's not
9 medically appropriate for this client. What I'm
10 asking to say is you can testify. You can say it's
11 affirmatively what it -- these, these questions that
12 you are trying to establish which is that it may have
13 been an adverse reaction to certain of these
14 ingredients but what you are trying to establish is
15 that she doesn't know whether or not he does or not
16 which establishes -- what I'm trying to do is --

17 MR. SIRI: Well, I'm moving on from there
18 already.

19 H.O. LEUNG: Yes.

20 MR. SIRI: I'm -- I, I was going to move on
21 to others, so.

22 H.O. LEUNG: Okay. Because what I'm doing
23 is, what I have been told by my supervisor is we need
24 to move on because if these are not -- what I'm
25 trying to do is prevent the other document

1 defaulting. That's what they are saying is that time
2 is of the essence in terms of getting these done.

3 So, --

4 MR. SIRI: Look, I -- I've got to put a
5 proper defense. This is not -- I, I, I just can't
6 stress enough. You know, you're, you're --

7 H.O. LEUNG: I think this hearing began --

8 MR. SIRI: The -- this --

9 H.O. LEUNG: -- over an hour ago, sir. And
10 I understand --

11 MR. SIRI: These people are just living in
12 their homes. They are just existing.

13 H.O. LEUNG: I understand.

14 MR. SIRI: And they are in violation for
15 existing --

16 H.O. LEUNG: Right.

17 MR. SIRI: -- as God created them. That's
18 literally what we're talking about here today.

19 H.O. LEUNG: And, and I'm not --

20 MR. SIRI: I, I, I, you know, and I --

21 H.O. LEUNG: I'm not -- listen.

22 MR. SIRI: -- I need to be able to make a
23 proper record not only for this hearing but also for
24 appeal.

25 H.O. LEUNG: And, and I think I've given

1 you the opportunity to make a proper record.

2 MR. SIRI: I would, I, I would say I have
3 not even touched on the medical appropriateness yet.

4 H.O. LEUNG: Okay. Well, I'm, I'm going to
5 ask you --

6 MR. SIRI: But, but, you know, I've -- if -
7 - you know, I would, I would say that -- let's look
8 at it this way. If you could carry over the record
9 from here to the other hearings, that will make it --

10 H.O. LEUNG: Yeah. I --

11 MR. SIRI: -- but, but I need an oppor-, I
12 need an opportunity to make my record.

13 H.O. LEUNG: Okay. You can make your
14 record, you can ask a couple more questions and then
15 we're going to have to move along.

16 DR. ROSEN: I'm sorry. Can I just answer -
17 -

18 MR. SIRI: Well, I, I have got to object, I
19 got to object to that.

20 H.O. LEUNG: You can object to anything you
21 want, that's okay.

22 MR. SIRI: I know. I'm, I'm just putting
23 on the record my objection that --

24 H.O. LEUNG: Alright.

25 MR. IRI: -- I've not been given enough --

1 asking just a few more questions is not, you know, I
2 strenuously object because I'm not being provided an
3 opportunity to create a record.

4 H.O. LEUNG: I understand your objection,
5 Counsel.

6 MR. SIRI: Okay. Alright.

7 Q: So, again, what company manufactures the MMR
8 vaccine that this order says my client should be injected
9 with?

10 H.O. LEUNG: You can answer that, go ahead.

11 DR. ROSEN: Merck.

12 Q: Merck. They are the only manufacturer, correct?

13 A: I can't comment on that.

14 Q: Okay. Do you know when the MMR vaccine was
15 licensed?

16 H.O. LEUNG: Counsel, I'm going to stop you
17 there because I, I don't -- you can make your
18 ultimate argument. If your ultimate argument is that
19 you believe this MMR is unsafe --

20 MR. SIRI: How can I make an ultimate
21 argument without a factual record, Your Honor?

22 H.O. LEUNG: Because what we're doing right
23 now --

24 MR. SIRI: I can -- you want me to just say
25 into the record it's not medically appropriate? How

1 do I do that without a factual record?

2 H.O. LEUNG: You can ask the doctor and you
3 can establish -- you can, you can --

4 MR. SIRI: You want me to just say is it
5 medically appropriate?

6 H.O. LEUNG: Well, what is your basis? I
7 mean, you can make --

8 MR. SIRI: I, I'm trying to establish
9 that.

10 H.O. LEUNG: You are trying to establish
11 what?

12 MR. SIRI: That it's not medically
13 appropriate but I need to get an opportunity to
14 question the doctor.

15 MR. MERRILL: I -- well, I object to the
16 term medically appropriate. That's not in the order
17 anyway.

18 H.O. LEUNG: Well, I, I --

19 MR. SIRI: It's in the violation. It's in
20 the summons. While you're looking at that, can I
21 just ask a few more questions?

22 H.O. LEUNG: Go ahead.

23 MR. SIRI: Okay. Well, I'm going to try to
24 -- I'll try to make this quicker.

25 Q: Can the MMR vaccine cause brain damage?

1 A: Serious allergic -- serious reactions to the MMR
2 vaccine are very rare.

3 Q: Please answer the question. Can the MMR vaccine
4 cause brain damage? Yes or no?

5 A: That is not, that is not a typical reaction of
6 the MMR vaccine.

7 Q: Can the MMR vaccine cause brain damage, yes or
8 no?

9 H.O. LEUNG: Okay. Counsel, I'm going to
10 just -- the reason why I'm doing this is as follow --

11 MR. SIRI: Can I make an application --

12 H.O. LEUNG: Yeah.

13 MR. SIRI: -- to have a deposition? And we
14 can come back another day --

15 H.O. LEUNG: Well, first off, this is --

16 MR. SIRI: -- after I have an opportunity
17 to create the record.

18 H.O. LEUNG: -- this is the Office of
19 Administrative Trials and Hearings. It's not a full
20 blown hearing and a full blown trial. So, the
21 procedures are streamlined for efficiency and to get
22 to the fact. There is no, there is no provision for
23 depositions.

24 MR. SIRI: Okay. Okay. So, you are
25 denying the application?

1 H.O. LEUNG: I am denying the application,
2 yes.

3 MR. SIRI: That's fine. So, I, I would
4 like to continue to question the witness.

5 H.O. LEUNG: Okay. I'm going to rule and
6 I, I don't mean to -- counsel, and let me just
7 establish, I don't even know what time this hearing
8 started. It's, it's almost noon now. I think it's
9 been over an hour. We have nine other cases. The
10 issue that I'm going to read here is the following,
11 on Page 2 of the order that is at issue here in the
12 summons, is that the child should be vaccinated
13 against measles and as such a parent or guardian
14 shall demonstrate that the child has immunity or
15 document to the satisfaction of the Department that
16 such child should be medically exempt from this
17 requirement. So, your questions right now regarding
18 whether or not the -- who made the MMR vaccine, does
19 it cause XY and Z damages, brain damage, it does not
20 go to the issue of whether or not the child had
21 immunity, whether he had the proper vaccination or
22 whether it was medically exempt.

23 MR. SIRI: Really?

24 H.O. LEUNG: Medic-, --

25 MR. SIRI: Why not?

1 H.O. LEUNG: Because medically exempt is an
2 issue and an affirmative defense that you can raise
3 by producing evidence that my client is medically
4 exempt for XY and Z reasons, and here is the doctor's
5 note or here is my doctor that says it's medically,
6 medically exempt. It's not by asking questions that
7 can be negated by this doctor saying, no, no, no to
8 every question you asked. It doesn't establish the
9 medical --

10 MR. SIRI: But you are assuming -- you, you
11 just assuming as --

12 H.O. LEUNG: I'm not assuming anything.

13 MR. SIRI: -- to my questions.

14 H.O. LEUNG: No, no.

15 MR. SIRI: They are not just no -- they are
16 not just no, no, no.

17 H.O. LEUNG: No, I'm, I'm assuming based
18 upon the chain of questions and the questions that I
19 have allowed that I should have stopped such as who
20 makes the vaccine. I mean, that's a discovery
21 question for a possible civil litigation and it has
22 nothing to do with whether or not, excuse me, the
23 child was vaccinated or whether --

24 MR. SIRI: But it, it is a predicate to the
25 documentation that shows --

1 H.O. LEUNG: Do you have --

2 MR. SIRI: -- Merck, Merck --

3 H.O. LEUNG: Okay.

4 MR. SIRI: I have, I have plenty of
5 documentations for Merck here.

6 H.O. LEUNG: Do you have documentation --

7 MR. SIRI: And I want to establish that
8 Merck created the vaccine --

9 H.O. LEUNG: Counsel, do you have
10 documentation showing whether or not this child is
11 medically exempt from the requirement or has the copy
12 of immunity?

13 MR. SIRI: Yes. It -- all of this that
14 were here shows that this child should not receive
15 the MMR vaccine. And I need to go through with this
16 doctor to establish it.

17 H.O. LEUNG: Okay. All of those documents
18 show what? Just tell me what it shows. And the
19 record should reflect that counsel is pointing to a
20 box full of documents. What will those documents
21 show? Just give me an offer of proof.

22 MR. SIRI: Sure. I mean, the offer of
23 proof shows that the, the -- that the risks of the
24 MMR vaccine outweigh the benefits for this child.

25 H.O. LEUNG: Okay. And how does that

1 address the following issues, whether or not the
2 child was vaccinated, whether or not the child had
3 the proper immunity or whether or not the child was
4 medically exempt?

5 MR. SIRI: It should be medically exempt
6 because the risks outweigh the benefit.

7 H.O. LEUNG: Okay. Okay. And it's through
8 questioning and what documents do you have to show
9 that the, the child --

10 MR. SIRI: I have the clinical trials of
11 the MMR. I have got all kinds of documents --

12 H.O. LEUNG: Okay.

13 MR. SIRI: -- regarding the product.

14 H.O. LEUNG: Please testified in a summary
15 faction as to what your evidence will show because I
16 want that to be in the record and I don't want to
17 exclude your evidence but I'm not going to allow you
18 to question this doctor as to every chain of science
19 leading up to whether or not the MMR vaccine is or is
20 not safe.

21 MR. SIRI: Well, you are assuming what I
22 was going to ask her.

23 H.O. LEUNG: I'm not assuming anything.
24 I'm just trying to expedite this hearing to give you
25 a fair hearing and also to allow you to produce the -

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MR. SIRI: Okay. So, is she going to get to respond to what I say?

H.O. LEUNG: It, it -- I made --

MR. SIRI: Because, because what -- okay, well then in that case, it's totally unfair and prejudicial. What you are saying to me is, I need to basically preview to the witness all of the arguments so that she can then be coached, --

H.O. LEUNG: Because, because it's just --

MR. SIRI: -- coached as to --

H.O. LEUNG: No, no.

MR. SIRI: -- what she is going to say.

H.O. LEUNG: Because this is a hearing and that --

MR. SIRI: Doctor should have to --

H.O. LEUNG: Counsel, let me just speak.

MR. SIRI: Yeah, I just --

H.O. LEUNG: Because this is a --

MR. SIRI: I want to finish my argument, that's it.

H.O. LEUNG: Because this is an expedited hearing in terms of us getting to the facts. It's not a trial. The, the rules and evidence are relaxed. I'm going to ask you to get to the

1 substance of what your evidence will show and I'm
2 giving you an opportunity to summarize it without
3 asking a hundred questions to the doctor. So, before
4 I close the hearing, I'm going to give you an
5 opportunity --

6 MR. SIRI: I probably could have gotten
7 through half of my outline at this point.

8 H.O. LEUNG: Okay, but we have been on
9 hearing for over an hour now and we have nine
10 additional hearings.

11 MR. SIRI: So, --

12 H.O. LEUNG: I'm sorry.

13 UNIDENTIFIED FEMALE: Can you pause the
14 audio?

15 H.O. LEUNG: Okay.

16 UNIDENTIFIED FEMALE: So, I could just
17 address all the parties.

18 H.O. LEUNG: Let me just pause this real
19 quick.

20 UNIDENTIFIED FEMALE: Alright.

21 H.O. LEUNG: Standby, no, it's not paused
22 yet, hold on. I'll tell you when it's paused.

23 UNIDENTIFIED FEMALE: Okay.

24 [OFF THE RECORD]

25 [ON THE RECORD]

1 H.O. LEUNG: Okay. The record should
2 reflect we are back on the record. We spoke with the
3 Assistant Director of Adjudication who came in and
4 determined that the substantive argument regarding
5 the constitutional arguments that have taken up a
6 long -- a significant amount of this hearing can be
7 transferred over to the subsequent hearings and we
8 are going to, in the other eight hearings, reference
9 the argument regarding that. And any -- Counsel, Mr.
10 Siri, as to the --

11 MR. SIRI: Yes.

12 H.O. LEUNG: -- other eight subsequent
13 hearings, to the extent, obviously, they are all
14 individualized with different children or
15 individuals, you can make your defenses individually,
16 just like you did in the beginning of this.

17 MR. SIRI: Right.

18 H.O. LEUNG: When we get to this argu-,
19 portion of the argument, you can just tell me on the
20 record that you are referencing the same arguments.

21 MR. SIRI: Absolutely.

22 H.O. LEUNG: Okay?

23 MR. SIRI: Got you.

24 H.O. LEUNG: So, --

25 MR. SIRI: And, and those others should go

1 real quick, very quickly.

2 H.O. LEUNG: And Mr. Siri, when I -- when
3 we last spoke before I paused the record, what I was
4 doing was, I was cutting you off and in the politest
5 way possible from asking additional questions of this
6 doctor to establish your offer of proof that the MMR
7 vaccine in your opinion and this is the substance of
8 your question, the benefits -- the health benefits do
9 not out-, outweigh the health risks and danger of the
10 MMR vaccine and you were going to ask questions to
11 this doctor to establish that. What I was trying to
12 tell you is that, is that you don't need to ask her
13 questions. You can, you can assert affirmatively
14 what you believe through your evidence, okay?

15 MR. SIRI: I understand. Which I, I --
16 just for the record, --

17 H.O. LEUNG: Yeah.

18 MR. SIRI: -- they are the one who issued
19 the violation and, you know, --

20 H.O. LEUNG: That's true.

21 MR. SIRI: And --

22 H.O. LEUNG: And I don't mean to cut you
23 off. That's true.

24 MR. SIRI: I understand your point.

25 H.O. LEUNG: However, you are asserting the

1 affirmative defense of, hey, this summons doesn't
2 apply to me because I know like -- I know this child
3 doesn't have the vaccine and I know there is nothing
4 in his record, and I am assuming it's him, that shows
5 that he has the immunity but it's not medically --

6 MR. SIRI: But with the, with the Health
7 Department because --

8 H.O. LEUNG: That he should be medically
9 exempt. And now, medically exempt is -- I am going
10 to ask the doctor. What is medically exempt and what
11 is the proof required for a medical exemption
12 according to the statute in the Department of Health?

13 DR. ROSEN: So, a provider would submit
14 documentation stating that a, a person has a
15 contraindication to receiving the MMR vaccine. There
16 is standard criteria. The Advisory Committee on
17 Immunization Practices and we have a copy of the
18 summary, outlines what contraindications are to
19 different vaccinations.

20 H.O. LEUNG: And is this a -- it has to be
21 a letter from a physician or --

22 DR ROSEN: Do you want to pull up the, the
23 wording from [unintelligible] [01:48:13]?

24 MR. SIRI: It's not what it says in the
25 order. It doesn't say anything about a letter from a

1 physician.

2 H.O. LEUNG: I understand that. I am just
3 asking what the definition of that term is, medical
4 exempt is. What is it?

5 DR. ROSEN: This would not be -- this would
6 not come from -- it's not a parent's decision about
7 having a contraindication. It would be coming from a
8 medical provider who deems this person to have a
9 medical contraindication and that contraindication
10 should be valid based on Advisory Committee on
11 Immunization Practice's national standards.

12 H.O. LEUNG: And Doctor, in your experience
13 in dealing with MMR cases, what has been an
14 acceptable medically -- what has been determined to
15 be medically exempt, acceptable proof of medical
16 exemption?

17 DR. ROSEN: So, criteria would include
18 somebody who is pregnant. There are very few
19 contraindications to the MMR vaccine.
20 Contraindications include pregnancy, someone who is
21 severely immunocompromised without -- for example,
22 somebody perhaps who is on chemotherapy or cancer
23 treatment, somebody who has a severe allergic
24 reaction to a vaccine, a document -- someone who has
25 documented severe allergic reactions to a vaccine

1 that they have received or a vaccine component
2 previously. So, this is a documented severe allergic
3 reaction and when we say severe, that mean something
4 that's life threatening, something like anaphylactic
5 reaction or someone who can't breathe, not, not a
6 rash, for example.

7 H.O. LEUNG: And so, the child cited in the
8 summons, and I don't mean -- I just have to -- as to
9 the child cited in the summons, we do not know for
10 certain whether or not this child has these
11 contraindications or does not have it. Is that
12 correct?

13 DR. ROSEN: We are left to assume that they
14 don't because they did not submit documentation as,
15 as outlined in the summons showing that they have the
16 medical contraindication. Medical contraindications
17 are very rare. Most people are eligible to receive
18 the vaccine.

19 H.O. LEUNG: Mr. Siri, can you ask your
20 questions of the doctor that go to the issue of
21 medical exempt as --

22 MR. SIRI: Sure.

23 H.O. LEUNG: -- as it's defined?

24 MR. SIRI: Sure.

25 Q: Can MMR vaccine cause brain damage?

1 A: That is not an expected reaction to the MMR
2 vaccine.

3 Q: Can it cause brain damage?

4 A: I siad that's not an expected reaction and just
5 for background, the safety of vaccines is monitored very
6 closely. Millions of doses of this vaccine have been
7 given as a routinely recommended vaccine.

8 MR. SIRI: I mean, can, can you direct the
9 witness to answer the question?

10 H.O. LEUNG: I am going to allow --

11 MR. SIRI: It's kind, it's kind of
12 difficult because it takes a while because I don't
13 get an answer.

14 H.O. LEUNG: Well, I am going to ask you
15 this and I am going to allow -- I allowed that
16 question but how does that go to the issue of
17 medically exempt because medically exempt, based upon
18 what the doctor testified to, is a doctor's note. I
19 mean, I am just going to lay it out. It's a doctor's
20 note from the child's physician saying that the
21 child's medical condition, as it existed at the time
22 the doctor wrote the note, exempts the child because
23 of some condition from [unintelligible] [01:50:58].
24 So, how does this question establish that?

25 MR. SIRI: You know, Your Honor, under,

1 under the City Charter, okay, it provides that the
2 City Charter says that and this is Section 104.9.5.
3 It says that Administrative Law Judge or Hearing
4 Officer may dis-, officer may dismiss a notice of
5 violation which interests of justice, when, and it
6 goes on to give criteria.

7 H.O. LEUNG: Okay. So -- okay.

8 MR. SIRI: Okay. So, there is also, I am
9 just adding on that there is also an interest of
10 justice here.

11 H.O. LEUNG: Okay.

12 MR. SIRI: And, and so, you know, that's a
13 proffered argument that I can make under City
14 Charter, and, and it -- all of this also goes to
15 that.

16 H.O. LEUNG: Okay. I understand that but
17 what I am trying to tell you is that I am asking you
18 to restrict your questions to the issue of medical
19 exempt. You can make the argument and you can
20 testify to as to why you believe in interest of
21 justice dismissal is appropriate. However, you are
22 asking questions such as the, you know, the make and
23 model, who makes it, that doesn't go to the issue of
24 medical --

25 MR. SIRI: I am just asking if, if the MMR

1 vaccine can cause brain damage.

2 H.O. LEUNG: Okay. And I'm, I'm, I'm
3 allowing her to answer [unintelligible] [01:52:06]
4 because I am not going to -- I know you want to --

5 MR. SIRI: Okay.

6 Q: Can MMR vaccine cause deafness?

7 A: I am not aware of the vaccine causing deafness.

8 Q: Can the MMR vaccine cause long term seizures?

9 A: I am not aware of it.

10 H.O. LEUNG: Counsel, again, --

11 MR. SIRI: I am almost done on that one.

12 H.O. LEUNG: Okay.

13 MR. SIRI: I am almost done. I am going to
14 give you evidence right now.

15 H.O. LEUNG: Go ahead.

16 MR. SIRI: I'm going to give you evidence
17 right now.

18 Q: Just, can MMR vaccine cause a child to enter into
19 a coma?

20 MR. SIRI: I can go fast. I just need to -
21 -

22 H.O. LEUNG: Okay.

23 MR. SIRI: -- give in some bandwidth
24 [unintelligible] [01:52:39] --

25 H.O. LEUNG: What I am going to do right

1 now, Counsel, I know you are going fast. I am going
2 to stop you there. I am going to stop you there
3 because, again, it's not addressing the issue on
4 whether this child --

5 MR. SIRI: How do you know? I haven't
6 asked my questions.

7 H.O. LEUNG: Because I have given you a lot
8 of leeway --

9 MR. SIRI: I, I've really not asked too
10 many question. We spent about 40 minutes arguing
11 about asking questions but I haven't actually asked
12 many questions.

13 H.O. LEUNG: The question that you just
14 asked, forget about the line of questioning. The
15 question that you just asked does not -- the specific
16 question you just asked --

17 MR. SIRI: Okay.

18 H.O. LEUNG: -- does not go to the issue of
19 whether or not this child has a medical exemption.

20 MR. SIRI: It, it goes to whether or not
21 the summons is appropriate. If they don't know the
22 condition of the child beforehand, they don't
23 understand what the vaccine can cause, what reactions
24 it can cause, how can they issue this order? Of
25 course, it's appropriate. They need to understand

1 what medical issues the vaccine can cause, what the
2 condition of the child is. And if they don't, how
3 are they issuing the summons?

4 H.O. LEUNG: Again, you are going to --
5 your, your question then --

6 MR. SIRI: It goes to injust-, --

7 H.O. LEUNG: Counsel, --

8 MR. SIRI: It goes to justice --

9 H.O. LEUNG: -- your question then goes to
10 the issue of why this summons should have been issued
11 in the beginning, which belies the fact that you just
12 told me that the -- I asked you to restrict the
13 question --

14 MR. SIRI: They are both, they are both.

15 H.O. LEUNG: Okay.

16 MR. SIRI: They are both. I know you want
17 to restrict it to that particular point but I
18 actually -- I have other arguments including
19 injustice under the Charter. There is that.

20 H.O. LEUNG: I understand. And one of your
21 arguments that you just made is that you asked the
22 question because you believe that this summons was
23 improperly issued to begin with. That they had no
24 basis to, to, to issue the summons.

25 MR. SIRI: That's right.

1 H.O. LEUNG: And again, I am going to deny
2 your request to ask that question because that
3 doesn't go to the issue that I ultimately have to
4 decide. I am not going to decide whether or not
5 there was a good cause basis to issue the summons. I
6 am going to tell you straight out. I am not going to
7 do that.

8 MR. SIRI: I, I get that.

9 H.O. LEUNG: So, the question is not
10 relevant for me making a decision. So, I am going to
11 stop you there and I am going to ask you to --

12 MR. SIRI: But it's -- it is relevant to
13 the question of injustice --

14 H.O. LEUNG: I understand.

15 MR. SIRI: -- under the Charter that you,
16 you can't rule on that.

17 H.O. LEUNG: I understand. And you've
18 asked the questions and you've -- I've allowed them
19 and I understand your argument.

20 MR. SIRI: I really haven't asked any
21 questions yet.

22 H.O. LEUNG: Your argument is that that the
23 summons does not conform to the interest of justice.
24 You don't have -- and your question, your line of
25 questioning goes to that. I understand that.

1 MR. SIRI: Can I -- then let me ask -- let
2 me ask some very quick questions, okay? Honestly, I
3 could have gotten through a lot of this already, you
4 know. So, let me just -- let me add here, I'll put
5 this into evidence.

6 H.O. LEUNG: What is, what is this? What
7 are you putting in?

8 MR. SIRI: This is from the CDC. This is
9 something called the vaccine information statement.

10 H.O. LEUNG: Respondent's 2, is it -- I
11 have marked and I am going to show it to counsel for
12 --

13 MR. SIRI: Here is a copy. Okay. Can I,
14 can I see a copy?

15 H.O. LEUNG: You can read that and let me
16 know. Hearing no objection, this is admitted.

17 **[Respondent's Exhibit 2 admitted into**
18 **evidence.]**

19 MR. SIRI: Okay. And, and this vaccine
20 information statement published by the CDC provides
21 that the risk of the MMR vaccine include deafness,
22 long term seizure, coma and brain damage, okay. And
23 I am going to --

24 H.O. LEUNG: As the hearing officer --

25 MR. SIRI: -- tie it all back to the

1 client. I just need to get there --

2 H.O. LEUNG: As the hearing officer, I am
3 taking that testimony in and I am, and I am
4 considering this in my decision. You have just
5 testified to something that's relevant. You are
6 saying that there is a Federal CDC printout that
7 shows that there is a danger to this MMR vaccine and
8 ultimately that issue goes to what -- about this
9 summons that you're, you're, you are saying that it
10 addresses.

11 MR. SIRI: It's not appropriate to issue it
12 but, but it needs to be --

13 H.O. LEUNG: I am sorry. Just --

14 MR. SIRI: It needs -- that it's -- that
15 the summons was unjust to issue but that -- not in a
16 vacuum obviously. That alone --

17 H.O. LEUNG: Does it go other than to --

18 MR. SIRI: To go to injustice?

19 H.O. LEUNG: It goes to the issue of
20 whether or not there is a medical exemption?

21 MR. SIRI: It, it goes to medical
22 exemption. It goes to the appropriateness of the
23 violations --

24 H.O. LEUNG: And how does it go to the
25 medical exemption? Just explain it to me so I can --

1 how does this CDC outline or whatever this form is,
2 go to the issue of medical exemption?

3 MR. SIRI: Okay. It goes to the question
4 of whether or not, at the end of the day, if you look
5 -- why don't -- when you look at the violation,
6 itself, okay. On the violation, it says, it says,
7 without the immunization -- it says document to prove
8 that immunization is not medically appropriate, okay.

9 H.O. LEUNG: Where are you reading from?

10 MR. SIRI: I am reading from the violation
11 itself.

12 H.O. LEUNG: The summons?

13 MR. SIRI: The summons.

14 H.O. LEUNG: Okay.

15 MR. SIRI: And so, I am trying to provide
16 you the documentation including the testimony --

17 H.O. LEUNG: Okay. But that's --

18 MR. SIRI: -- it's not medically
19 appropriate. And I know what you want. You want me
20 to go get some doctor's note. You --

21 H.O. LEUNG: No, no, no.

22 MR. SIRI: -- to, to do that --

23 H.O. LEUNG: It's not a medical -- these
24 are two different stamps.

25 MR. SIRI: And it --

1 H.O. LEUNG: What's contained on the
2 summons is it what I have to decide. What I have to
3 decide is whether or not the law -- the order was
4 complied with in the sense that the child was either
5 vaccinated, had the proper immunity or was medically
6 exempt. And what you are showing me -- what I am
7 trying to do is, I am not denying you presenting
8 evidence. What I am trying to say is that what you
9 are giving me tied into one of those three things.
10 Oh, fourth, interest of injustice, right.

11 MR. SIRI: And interest of justice as well.

12 H.O. LEUNG: So just -- when, when you give
13 me some -- all I am asking is what --

14 MR. SIRI: Okay.

15 H.O. LEUNG: What pigeon hole are you
16 putting this into?

17 MR. SIRI: Understood.

18 H.O. LEUNG: Are you putting it into
19 interest of justice pigeon hole or are you putting it
20 into -- that's all I am asking.

21 MR. SIRI: In-, right, interest of justice,
22 appropriateness of the summons --

23 H.O. LEUNG: Okay. Appropriateness of the
24 summons is something that --

25 MR. SIRI: Because -- yeah, so there is

1 three. There is interest of justice.

2 H.O. LEUNG: Okay.

3 MR. SIRI: There is the appropriateness of
4 the summons because you have to have a factual
5 background, meaning they, they have -- they should
6 have basic knowledge regarding the product they are
7 saying the child should be injected with and the
8 child.

9 H.O. LEUNG: Okay. Appropriateness of the
10 summons --

11 MR. SIRI: Summons and the third is --

12 H.O. LEUNG: Interest of justice and what's
13 the third?

14 MR. SIRI: And, and then -- and, and
15 medically appropriate.

16 H.O. LEUNG: Medically appropriate.

17 MR. SIRI: Or what do you call, medical
18 exemption, whatever you want to call it.

19 H.O. LEUNG: Okay. Okay.

20 MR. SIRI: Okay.

21 H.O. LEUNG: Fine. That's fine.

22 MR. SIRI: And, and, and the interest of
23 justice has a sub-point that they have not -- that --
24 you know, I am going to present you evidence that
25 they can't substantiate that the risks -- that, that

1 the benefits outweigh the risks.

2 H.O. LEUNG: Okay.

3 MR. SIRI: They are going to substantiate
4 that.

5 H.O. LEUNG: Okay. I have, I have let you
6 make the argument --

7 MR. SIRI: Yes.

8 H.O. LEUNG: -- that the benefit does not
9 outweigh the risk.

10 MR. SIRI: Yes.

11 H.O. LEUNG: And I have allowed you to
12 present some documents. Is there any other documents
13 you want to present or any evidence you want to
14 present?

15 MR. SIRI: Yes.

16 H.O. LEUNG: Okay. Go ahead.

17 MR. SIRI: Okay. So, the next document I
18 am going to present requires a little bit of
19 testimony, probably four questions. Can I ask the
20 witness?

21 H.O. LEUNG: Yes. What are the bases of
22 the questions? I mean, I just -- what -- go ahead.
23 Start the questioning.

24 MR. SIRI: Okay.

25 Q: Okay. Just so we have -- we know what we are

1 talking about here. Alright. I just want to make sure we
2 are on the same page about what we are talking about.

3 This is an MMR vaccine container, right?

4 A: Correct.

5 Q: Okay.

6 H.O. LEUNG: The record should reflect that
7 Mr. Siri is holding up an MMR vaccine container.

8 Q: Okay. And this is a dose of MMR, one that was --
9 that you would give to one child, correct?

10 A: It's a vial of MMR vaccine.

11 Q: That would be administered to a child under the
12 order, to comply with the order, this is what they would
13 need to be injected with, correct?

14 A: Correct.

15 Q: Okay. And this, and this is -- so you can see
16 what it is, this is a vial of MMR without the label on it.
17 So, you can see it's, it's actually some powdered form,
18 okay. This powdered form, it gets reconstituted with,
19 with, with liquid solution before it's injected, right?

20 A: Correct.

21 Q: Okay. Okay. And this is the typical needle that
22 you used to do that?

23 A: Correct.

24 Q: Okay. I am going to use the appropriate
25 procedure for putting it back on. I think I did that

1 right. That's an unopened one, okay. Before this product
2 was licensed in 1978, it underwent a clinical trial,
3 right? Three more questions.

4 H.O. LEUNG: I am going to -- no, no,
5 Counsel. I am stopping you right there.

6 MR. SIRI: Okay. Let me get the clinical
7 trial --

8 H.O. LEUNG: Get, get through your
9 testimony.

10 MR. SIRI: Give, give me, give me Exhibit
11 175. I don't know how I can do this without
12 testimony but I mean, I, I am just going to --

13 H.O. LEUNG: Counsel, you're going to do it
14 --

15 MR. SIRI: -- object for the record.

16 H.O. LEUNG: You can object it. Counsel,
17 you can put your objection on the record.

18 Q: Not 175, so 3 -- Exhibit 317, as the exhibit is
19 being pulled out, to have a proper clinical trial, you
20 need thousands -- tens of thousands of participants who is
21 properly [unintelligible] [02:00:14] to get specifically
22 significant results, correct?

23 H.O. LEUNG: I am going to object --
24 Counsel, I am not going to let you ask her the
25 foundation of how the MMR vaccine came to existence,

1 the clinical trials, the positives or negatives of
2 it.

3 MR. SIRI: Why not?

4 H.O. LEUNG: I am going to allow you to
5 testify --

6 MR. SIRI: Doesn't that go to all four of
7 the points we just talked about?

8 H.O. LEUNG: No, no, I am going to allow
9 you to testify as to that and I am going to allow you
10 to present evidence as to that.

11 MR. SIRI: Okay. But she -- okay, so if
12 that -- alright. If I am going to do it that way, I
13 want to make sure -- I want, I want a directive that
14 she doesn't have an opportunity to actually then
15 opine on it because what's going to happen is, is all
16 I am --

17 H.O. LEUNG: Counsel, I am not going to
18 make a preliminary ruling as to what another witness
19 can or cannot. I am not going to bar them from
20 doing. You can make an application at the end of
21 your presentation, if they start talking and you
22 could say, that's inappropriate, I don't want them to
23 talk and I will make an application but you can't bar
24 them. I can't put a restriction --

25 MR. SIRI: But you are barring me from,

1 from asking her questions.

2 H.O. LEUNG: No, I am not ask, I'm not --

3 MR. SIRI: But you don't want to bar her
4 from, from that -- from, from the counsel.

5 H.O. LEUNG: I'm not --

6 MR. SIRI: Okay. I am fine with -- if you
7 want to bar me from asking questions, I will offer my
8 proffers of proof. Can I just make my, make my
9 objection on the record?

10 H.O. LEUNG: No, no, --

11 MR. SIRI: But, but I would like similar
12 directive that counsel for the DOB cannot also ask
13 questions.

14 H.O. LEUNG: Let me just, let me just put
15 on the record. I am not barring you from asking
16 questions. I am barring you from asking questions
17 that are not relevant --

18 MR. SIRI: They go to the fourth point.

19 H.O. LEUNG: I understand. You disagree
20 with me.

21 MR. SIRI: Yes.

22 H.O. LEUNG: You think they are relevant.
23 I think they are not relevant --

24 MR. SIRI: I am just making, I am just
25 making a record.

1 H.O. LEUNG: I understand.

2 MR. SIRI: I should make a record.

3 H.O. LEUNG: I am barring you from asking
4 questions and I have given you a lot of leeway that I
5 believe is not relevant to my ultimate determination
6 as to the facts of this case. That's what I am
7 barring you from. I am not barring you summarily
8 from asking questions because (a), I don't like you
9 or (b), because I think you are not --

10 MR. SIRI: I didn't think you did.

11 H.O. LEUNG: No. I am barring you because
12 --

13 MR. SIRI: You just seem very nice.

14 H.O. LEUNG: I am barring you because I
15 believe the line of questioning is not relevant.
16 Simple.

17 MR. SIRI: Okay.

18 H.O. LEUNG: That's it, nothing personal.
19 And to the extent that you are telling me that they
20 cannot ask questions, I don't even know what the
21 questions are. If it's not relevant, I'll bar them
22 but if it is relevant, I'll allow it. You're telling
23 me to, to put a gag over them before they can --

24 MR. SIRI: Yeah, but --

25 H.O. LEUNG: No.

1 MR. SIRI: -- you --

2 H.O. LEUNG: What I am telling you right
3 now is, you can present evidence, any evidence you
4 want. I am not barring you from anything. But if
5 you ask questions that are not relevant, I will stop
6 you. And I have given you a lot of leeway.

7 MR. SIRI: Okay. So, I hope the same
8 standard of relevance that you are applying will
9 apply to them too.

10 H.O. LEUNG: It will, it will. I guarantee
11 it will.

12 MR. SIRI: Because I can't see what
13 possible questions can be asked.

14 H.O. LEUNG: I guarantee it will and to the
15 extent that you believe that they ask a question
16 that's not relevant, you object and I'll make a
17 ruling.

18 MR. SIRI: So, they -- okay. So, any
19 question regarding the safety or efficacy is not
20 relevant, right?

21 H.O. LEUNG: Present your evidence.

22 MR. SIRI: Okay. Okay. This is a copy of
23 the clinical trial summary by the FDA relied upon to
24 license.

25 H.O. LEUNG: How many pages are in that,

1 Counsel, approximately?

2 MR. SIRI: Two hundred and fourteen.

3 H.O. LEUNG: Okay. So, what are you giving
4 that to me for?

5 MR. SIRI: This --

6 H.O. LEUNG: What's the purpose? What is
7 the [unintelligible] [02:02:52]? Where does it go?

8 MR. SIRI: Yeah, this goes into all four of
9 the arguments.

10 H.O. LEUNG: Okay.

11 MR. SIRI: All four. Everything I am going
12 to give you right now --

13 H.O. LEUNG: Yes.

14 MR. SIRI: -- goes into all four of those
15 arguments.

16 H.O. LEUNG: This 200 plus paged document
17 will be marked as Respondent's 3, I am sorry,
18 Respondent's 4.

19 MR. SIRI: Or you know, let me -- do we
20 have a summary? Do you have --

21 H.O. LEUNG: Did you give me two separate
22 documents of this or are they just one?

23 MR. SIRI: No, Your Honor. Just --

24 H.O. LEUNG: This is one? Okay. So, this
25 is Respondent's 4.

1 MR. SIRI: 317?

2 MR. MERRILL: Do you have a copy of
3 [unintelligible] [02:03:16]? Okay.

4 MR. SIRI: You know what? I've got just
5 the relevant trials from that. I could give you a
6 shorter version. Would you prefer that?

7 H.O. LEUNG: You can give me whatever you
8 want, Counsel.

9 MR. SIRI: Okay.

10 MR. MERRILL: Can I access further what
11 this is?

12 MR. SIRI: No, 316 --

13 H.O. LEUNG: Can you summarize what those
14 200 pages says?

15 MR. SIRI: That is the FDA summary of the
16 clinical trial relied upon to license the MMR2
17 vaccine that the order is saying should be injected
18 into my client.

19 H.O. LEUNG: Okay. And, and, and make an
20 argument for me as, as the finder of fact. What is -
21 - what do you think that supports?

22 MR. SIRI: Sure. So, when you look at this
23 clinical trial, clinical trials in order to be, and I
24 was going to do this through the witness, but
25 clinical trials in order to be, they, they need to

1 usually have a few elements. One, they are -- they
2 typically have a control group, right, you can --

3 H.O. LEUNG: Okay. Just, just summarize
4 what those 200 plus pages say. You don't have to
5 testify as to what -- what does it say?

6 MR. SIRI: What it shows is that there were
7 only 800 or so participants in the clinical trial.

8 H.O. LEUNG: Alright.

9 MR. SIRI: That's underpowered so you
10 cannot reach statistically --

11 H.O. LEUNG: And therefore, --

12 MR. SIRI: -- significant result.

13 H.O. LEUNG: -- the MMR vaccine is
14 dangerous. Is that what you are saying?

15 MR. SIRI: No, I didn't say that.

16 H.O. LEUNG: Okay.

17 MR. SIRI: And they looked at safety for 42
18 days.

19 H.O. LEUNG: Okay.

20 MR. SIRI: So, you couldn't find out what
21 the long term adverse events were, okay, and they had
22 no control group. So, you couldn't properly compare
23 what the difference between getting the MMR and not
24 getting the MMR was. So, they were underpowered, was
25 not -- and was not -- and was only a 42 days of

1 safety review --

2 H.O. LEUNG: Mr. Siri, and I am going to --

3 MR. SIRI: -- and --

4 H.O. LEUNG: -- ask you to get to the end
5 therefore.

6 MR. SIRI: And therefore, therefore, it's
7 more evidenced towards the four points and I am
8 building the case right now, Your Honor.

9 H.O. LEUNG: But I don't understand what
10 the -- does that support any theory? Does it show
11 that it's safe --

12 MR. SIRI: What it, what it shows is that -
13 - what it shows is that before it was licensed, okay,
14 it shows two things. One, you didn't know what the
15 long term adverse reactions to this product was
16 before it was licensed.

17 H.O. LEUNG: Okay.

18 MR. SIRI: One, undisputable, I don't think
19 she would dispute if I could ask her because it only
20 says 42 days. Two, when you look at the actual, it
21 was eight little clinical trials and it has the
22 adverse reactions and I'd like to submit this. So,
23 this is a summary of just taking out --

24 H.O. LEUNG: This is a -- how many pages
25 would you say this is here?

1 MR. SIRI: I don't know, 25. This is just
2 a relevant --

3 H.O. LEUNG: I'm going to mark this as P4.

4 MR. SIRI: Okay. So when you look --

5 MR. MERRILL: This is of part of three,
6 that's not four?

7 MR. SIRI: It's part of 3, that's right. I
8 wanted to --

9 H.O. LEUNG: This is all part of that?

10 MR. SIRI: Yeah, I want --

11 H.O. LEUNG: Okay. I am sorry.

12 MR. SIRI: I, I'm, I'm --

13 MR. MERRILL: I think we should mark it as
14 an exhibit. It seems to be the relevant --

15 MR. SIRI: It's a relevant parts but I --
16 you know, for, for --

17 H.O. LEUNG: I am going to mark as P4 and
18 P5. Any objection from the Department?

19 MR. MERRILL: No, I haven't seen it but.

20 H.O. LEUNG: Yeah.

21 **[Respondent's Exhibit 4 admitted into**
22 **evidence.]**

23 MR. SIRI: For completeness, I mean, I am
24 fine with with-, withdrawing this if you just want
25 that. You don't have to deal with a copy and that's

1 just the relevant part.

2 H.O. LEUNG: No, that's okay. We'll take
3 everything you have but I would like you to summarize
4 what this --

5 MR. SIRI: Yeah.

6 H.O. LEUNG: -- is telling.

7 MR. SIRI: Let me get, let me get the
8 document here. Take, take a copy, please. Okay.
9 So, now, if you, if you look at -- so, this is what
10 you see now. Go to the third page please, okay. On
11 the third page, this is the summary --

12 H.O. LEUNG: Well, are they following
13 along? Do you have this?

14 MS. PEONE: No, Your Honor. I don't have a
15 copy of it.

16 MR. MERRILL: No, Your Honor.

17 MR. SIRI: Do you have a copy? Here you
18 go.

19 MR. MERRILL: This is 4?

20 H.O. LEUNG: This is Petitioner's 4 and
21 that Petitioner's 4 is the Department of Health and
22 Education and Welfare bate stamped September 15,
23 1978, a letter [unintelligible] [02:06:15] Dr. Grey
24 [phonetic] from Dr. Marlin [phonetic]. Go ahead.

25 MR. SIRI: Okay. Let me get the

1 [unintelligible] [02:06:20] request. So, so, is
2 there -- I just want to make sure -- this is the, the
3 clinical trial relied upon to license this product by
4 the FDA. If there is any objection to that, I also
5 have the --

6 H.O. LEUNG: Counsel, there is no
7 objection.

8 MR. SIRI: Okay.

9 H.O. LEUNG: What I want you to do is just
10 get to the summary part of this.

11 MR. SIRI: Next third page -- if you go to
12 the third page, you could see it's the summary of the
13 clinical trials, okay. And you could see there are
14 one, two, three, four, five, six, seven, there are
15 eight, there are eight basically studies. And you
16 could see the total participants of 834 individuals.
17 Do you see that?

18 H.O. LEUNG: I do.

19 MR. SIRI: Okay. So, that's the total
20 number of individuals that received the MMR to
21 license this product, okay. And if you look at the
22 summary, there was no control group that was used.
23 There's no placebo control group. So, they weren't
24 comparing it to anything. Please turn to the next
25 page and let's look at the adverse reactions from the

1 MMR vaccine in this trial. Please turn down to upper
2 respiratory illness. Do you see that?

3 H.O. LEUNG: Yes.

4 MR. SIRI: Okay. Do you see in zero to
5 four days, 60 -- 39.6 percent of the children in the
6 trial had an upper respiratory illness after getting
7 MMR. Between five and 12 days, 38.5 percent, those
8 are very significant numbers of children that had
9 respiratory illness in this trial. If you go down
10 and look at gastro-intestinal illness, similarly, you
11 can see the number of children that had gastro-
12 intestinal illness following the MMR vaccine, right?
13 One of the things that they are complaining about in
14 the order is that M -- the measles can cause
15 pneumonia and, and, and diarrhea.

16 H.O. LEUNG: Mr. Siri, can I stop you
17 there?

18 MR. SIRI: Yeah.

19 H.O. LEUNG: Does the child in question in
20 this have any of these adverse reactions?

21 MR. SIRI: He hasn't received the MMR
22 vaccine, Your Honor.

23 H.O. LEUNG: Okay. He is --

24 MR. SIRI: Okay. So, how can he -- he
25 hadn't received it yet.

1 H.O. LEUNG: Okay.

2 MR. SIRI: He, he could.

3 H.O. LEUNG: Does he have a doctor who can
4 testify or have -- does he have a record?

5 MR. SIRI: There is a doctor right here,
6 Your Honor.

7 H.O. LEUNG: No, no, no. Does the child
8 have a doctor that can attest to the fact that this
9 child taking this vaccine would be detrimental to his
10 health?

11 MR. SIRI: Does the -- there is an
12 obligation for him to go do that?

13 H.O. LEUNG: Well, I am trying --

14 MR. SIRI: I mean --

15 H.O. LEUNG: There, there is an obligation
16 in the sense that --

17 MR. SIRI: There is an obligate --

18 H.O. LEUNG: There is an obligation in the
19 sense that your client received the summons alleging
20 a failure to immunize and that the defense, the
21 allegation specifically says that he wasn't immunized
22 as required by law, didn't have proper tests showing
23 that he had proper immunity albeit see any
24 documentation showing that there is a proper
25 exemption.

1 MR. SIRI: Yeah. I am showing that it's
2 not medically appropriate to give this child when you
3 look at the clinical trials, when you look at the
4 post licensure safety studies conducted by the
5 Institute of Medicine and the CDC which you find --

6 H.O. LEUNG: So, you are saying that
7 summons should not -- this is an argument in the
8 cubby hole that it should not have been issued. Is
9 that correct?

10 MR. SIRI: I am -- no, I am saying it's --
11 I am saying that even the summons on its face says it
12 should be medically appropriate. You are say --
13 adding the requirement that a doctor issue it. I
14 don't know why that's required --

15 H.O. LEUNG: Okay. So, you're saying --

16 MR. SIRI: -- all of a sudden.

17 H.O. LEUNG: -- it's not medically -- so,
18 you are saying that this supports the idea that it's
19 --

20 MR. SIRI: The four, the four buckets.

21 H.O. LEUNG: Okay.

22 MR. SIRI: It's unjust, it's the risks
23 outweigh the benefits, it's not medically
24 appropriate. Right, you know the four.

25 H.O. LEUNG: I have it. Anything else?

1 MR. SIRI: You have it. Okay. You, you
2 will continue -- if you go through this, you will see
3 all of that for all of these, okay?

4 H.O. LEUNG: Okay. Anything else in terms
5 of this document?

6 MR. SIRI: Yeah. Well, well, here is the
7 thing, I'd like to be accepted that, you know, I made
8 a representation but it's just counsel saying it.
9 The doctor would have said it. What is a properly
10 powered study? What is, what is a placebo control?
11 But I didn't have a chance to do that. So, I am
12 going to leave it then. Obviously, she shouldn't
13 have a chance to now go and, you know, say stuff
14 afterwards, after the fact now that she is given a
15 preview of the argument. She shouldn't have an
16 opportunity to say it beforehand when she would have,
17 you know, not, not being a preview of the arguments
18 when truth was original to her.

19 H.O. LEUNG: Right. I, --

20 MR. SIRI: It's no longer original to her.

21 H.O. LEUNG: I won't hear any arguments or
22 testimony or questions from that.

23 MR. SIRI: Well, because we are not,
24 because we are not there yet.

25 H.O. LEUNG: Okay.

1 MR. SIRI: Okay. Now, when the 1986 act
2 was passed, okay, I am going to read two sentences
3 from two provisions of law into the record, okay.
4 One is the 198-, the National Vac-, Childhood Vaccine
5 Act 1986 was provided -- was codified at 42USE300AA-1
6 through 34. I am going to read you one sentence from
7 that act. It says, "No person may bring a civil
8 action for damages in the amount greater than \$1,000
9 or an unspecified amount against a vaccine
10 administrator or a manufacturer in a State or Federal
11 Court for damages arising from a vaccine related
12 injury or death." That was in 1986. The reason that
13 act was passed was because of all the harm being
14 caused by vaccines at that time. There was only one
15 manufacturer left for MMR, DTaP and polio. Those are
16 the only two vaccines at the time. They were going
17 bust. The US Supreme Court [unintelligible]
18 [02:10:43] said that the amount of damages, the
19 amount of liability was 200 times the amount of
20 revenue from the DTP vaccine at that time. MMR was
21 having a similar problem. So, instead of letting --
22 than make a better, safer vaccine, what Congress did
23 is give them immunity from liability for their
24 injuries. Okay?

25 H.O. LEUNG: I understand your argument.

1 MR. SIRI: And the US Supreme Court then
2 [unintelligible] [02:11:02] said, just, just so you
3 know, read one sentence, "We hold that the National
4 Childhood Vaccine draft pre-empts all design defect
5 claims against vaccine manufacturers brought by
6 plaintiffs who seek compensation for injury or death
7 caused by vaccine, side-effects." And so, that is
8 what the 1986 did and what it did is it, it, it
9 removed the market forces that drive vaccine safety
10 instead of making health departments responsible for
11 vaccine safety. They sit in that shoes, actually the
12 Federal Health Authorities or the CDC does. Now,
13 after the 1980 -- when the 1986 act was passed, one
14 of the things it did is it actually told HHS, you
15 need to look at whether some of these vaccines cause
16 certain injuries. HHS then went in turn hired the
17 Institute of Medicine to conduct that review, okay.
18 In that review, can I get the Exhibit 39 please?
19 Okay. The IOM issued its first report in 1991,
20 alright. In that report, it looked at four commonly
21 claimed serious injuries from the Rubella component
22 of this vaccine, okay. And what it found was that
23 two of those commonly reported conditions are caused
24 by the vaccine, alright. The Rubella component of
25 the vaccine, one of those, okay, is --

1 H.O. LEUNG: I am going to mark as
2 Respondent's 5 the adverse affects of Rubella
3 vaccines and Pertussis, okay.

4 MR. SIRI: Pertussis.

5 H.O. LEUNG: Pertussis.

6 MR. SIRI: Okay. And so, if you turn to
7 the second to last page please, okay.

8 H.O. LEUNG: Any objection to R5 being
9 admitted?

10 MR. MERRILL: Something -- sure.

11 H.O. LEUNG: Hearing no objection --

12 **[Respondent's Exhibit 5 admitted into**
13 **evidence.]**

14 MR. SIRI: The Institute of Medicine, I
15 mean, you know, and HHS has done a paper.

16 MR. MERRILL: Yeah.

17 MR. SIRI: So, if we go to the second last
18 page which you can see is, this is the, this is the
19 summary of conclusions, okay. So, under the Rubella
20 vaccine which is, which is what's in here, RA 27/3,
21 it's made with human diploid cells from aborted fetal
22 tissue. It says evidence insufficient to indicate.
23 So, they didn't -- there was no evidence one way or
24 another whether or not it causes radionuclides and
25 other neuropath -- neuropathies with thrombocytopenic

1 purpura, okay. But it was -- evidence was consistent
2 with the cause or relationship or indicated cause and
3 relation for chronic arthritis and acute arthritis,
4 okay. The next report issued by the IOM was then in
5 1994. That's Exhibit 314, okay. And what the IOM
6 this time looked at, they looked at the Rubella
7 component. As you know, the MMR stands for Measles,
8 Mumps, Rubella so they looked at the Rubella
9 component in the 1991 report. In the 1994 report,
10 they looked at the mumps and the measles component
11 and what they did in that report is they looked at
12 the 22 most commonly claimed serious adverse
13 reactions after that vaccine. And what they found in
14 that report is --

15 H.O. LEUNG: Respondent's, Respondent's 6
16 is what counsel is going to read from. If there is
17 any objection by the Health Department, let me know.

18 MR. MERRILL: No.

19 H.O. LEUNG: No objection. This is
20 admitted. Go ahead.

21 **[Respondent's Exhibit 6 admitted into**
22 **evidence.]**

23 MR. SIRI: Okay. So, if you go to that one
24 and you go to the fourth -- if you go to the fourth
25 last page, this is the summary of causality table,

1 okay. And so, here they said, okay, these are the
2 conditions we know we believe are caused by it.
3 These are the ones we, we would believe are not
4 caused by it and these are the ones we don't know.
5 And what you are going to find is, and it's very
6 troubling, is that for 18 of them, for 18 of them,
7 the IOM said, you didn't do the science. We don't
8 know. Even though they are commonly reported, we
9 don't know whether or not the measles and mumps
10 component cause encephalopathy which by the way, they
11 later found out it did, that's brain damage as you
12 saw. Or sub-acute sclerosis or septic meningitis or
13 residual seizure and sterility or optic neuritis,
14 right, damage to the nerves in the eyes, right. Do
15 you see that under mumps and measles and mumps, on
16 the fourth last page, fourth last page? May -- can I
17 lean over, Your Honor, --

18 H.O. LEUNG: Yes.

19 MR. SIRI: -- let me help you out there, is
20 that okay?

21 H.O. LEUNG: Yeah.

22 MR. SIRI: I don't want to get into your
23 space too much.

24 H.O. LEUNG: Okay.

25 MR. SIRI: So, so, here is, here is the,

1 here is the measles and the mumps. The Category 1 is
2 no evidence bearing. Category 2 is the evidence
3 inadequate to accept or reject and you can see under
4 the measles and mumps, there were -- science wasn't
5 conducted to figure out, were these things or were
6 they not caused by the measles or mumps.

7 H.O. LEUNG: Okay.

8 MR. SIRI: Okay.

9 H.O. LEUNG: Got you.

10 MR. SIRI: Okay. Now, if you go to the
11 next page, you can also see the evidence favors
12 rejection. So, for -- there is nothing that was
13 rejected and the favor did accept causation for
14 anaphylaxis for the, for the measles vaccine.

15 H.O. LEUNG: Okay. So, any other evidence
16 you have?

17 MR. SIRI: Okay. Yeah, and then there is
18 another page that were also accepted for
19 thrombocytopenia as well as, as well as death. Death
20 can result from the measles vaccine according to the
21 Institute of Medicine, okay. Now, what the IOM said
22 in this report was, read one sentence, "The lack of
23 adequate data regarding many of the adverse events
24 under study was a major concern to the committee."
25 They said, hey, HHS, do your job, you got to do

1 studies to find out, do this -- does this vaccine
2 does it or does it not cause death. But you know
3 what HHS is? HHS solves the responding Vaccine Corp.
4 If it does any study that shows that the vaccine
5 causes harm. Well, what happens is that we use
6 against it in Vaccine Corp. So, under the 1986 act,
7 you can sue them for a vaccine injury. But the
8 respondent is the Department of Health Mental
9 Services and the vaccine [unintelligible] [02:16:01].

10 H.O. LEUNG: Counsel, I am going --

11 MR. SIRI: I am moving on. I am moving on.

12 H.O. LEUNG: No, no, I am -- before we move
13 on, how many more documents do you have,
14 approximately? Just give me approximate.

15 MR. SIRI: Maybe a dozen, two.

16 H.O. LEUNG: Dozen, okay. I am going to
17 ask --

18 MR. SIRI: I am going to go quickly.

19 H.O. LEUNG: No, I am going to ask you to
20 mark them from R7. Mark them all, R7 upwards.

21 MR. SIRI: Exhibit 33 --

22 H.O. LEUNG: And then I am going to ask you
23 to give them to me in mass and I am going to ask you
24 to read into the title of it and I am going to take
25 it. What I don't want you to do is right now, I am

1 allowing you to make a record but --

2 MR. SIRI: Forty three --

3 H.O. LEUNG: -- I am going to make -- my
4 determination and my instinct right now is that this
5 is not relevant to the three issues of whether or not
6 the child was vaccinated, whether or not he had
7 tested immunity and whether or not there was a
8 medical exemption. So, I am going to ask you to mark
9 them if you can, R7, starting with R7 upwards.

10 MR. SIRI: Sure. R7, so this is a report
11 from 2012. This looked at 31 commonly claimed
12 injuries from the MMR, and R7?

13 H.O. LEUNG: Yes.

14 **[Respondent's Exhibit 7 admitted into**
15 **evidence.]**

16 MR. SIRI: And this one found that six of
17 them were caused by MMR but 23 of them, they have no
18 idea. Again, IOM said, hey, why aren't you doing the
19 science that's needed Exhibit 4 --

20 H.O. LEUNG: This is, this is the same part
21 --

22 MR. SIRI: Exhibit 48 --

23 H.O. LEUNG: Okay. This is your copy here.
24 Okay. Then that comes.

25 MR. SIRI: Wait a second. This is -- well,

1 wait a second. I am sorry. Did I just lose that 43?
2 Yeah, let me, let me get 48. So, R8. So, the R8 is
3 an excerpt from the 1998 IOM report in which it says,
4 "The committee was able to identify little
5 information pertaining to why most individuals react
6 adversely to vaccines when most do not," okay. And
7 so, what it did is, it said, hey, you got to do the
8 studies for which children are going to be
9 susceptible to injury.

10 **[Respondent's Exhibit 8 admitted into**
11 **evidence.]**

12 H.O. LEUNG: Right.

13 MR. SIRI: Okay. And this is a report.
14 This is Exhibit 49. And so this is, you know, 2012,
15 over a dozen years later, the IOM again looked at
16 this issue and it said, both epidemiological and
17 mechanistic research suggest that most individuals
18 who experience an adverse effect of vaccines have a
19 pre-existing susceptibility. These pre-dispositions
20 can exist for a number of reasons, genetic variance,
21 okay, environmental exposures, behavior, intervening
22 illness, developmental stages, all of which can
23 interact or suggest it graphically. Some of these
24 adverse effects are specific to the particular
25 vaccine while others may not be. Some of these

1 predispositions may be detectable prior to
2 administration of vaccines. Much work remains to be
3 done to elucidate and to develop strategies to
4 document the epidemiology mechanisms that lead to
5 adverse effects in individual patients. What they
6 are saying is vaccines, MMR can cause. We, we can
7 identify which children will be injured but you
8 haven't done the science to figure that out. Let me
9 get a -- let me get Exhibit 225, okay. I would like
10 to ask, I would like to ask whether or not they know
11 if the child is genetically predisposition that would
12 render them susceptible to an adverse reaction to MMR
13 but yeah, I have seen your objection stands. Because
14 for example, here is, here is a study that identifies
15 specific genetic markers for when a child will have a
16 seizure, will have seizures after the MMR vaccine.

17 H.O. LEUNG: Okay.

18 **[Respondent's Exhibit 9 admitted into**
19 **evidence.]**

20 MR. SIRI: This is conducted by a reputable
21 peer review science, mainstream journal by
22 institutions.

23 H.O. LEUNG: Counsel, I appreciate you
24 commenting --

25 MR. SIRI: Yeah, that's going -- so, this

1 is R, what is this, R10?

2 H.O. LEUNG: R10, I'm going to move into
3 evidence.

4 **[Respondent's Exhibit 10 admitted into**
5 **evidence.]**

6 MR. SIRI: Exhibit 340 --

7 [CROSSTALK]

8 H.O. LEUNG: I would give you an
9 opportunity to submit the evidence and comment on
10 what it says and what it is --

11 MR. SIRI: I mean, look, I'm doing it in
12 this fashion, Your Honor, but I -- my objection
13 stands that this is not --

14 H.O. LEUNG: I understand your objection.

15 MR. SIRI: -- appropriate for me to be able
16 to make a proper record.

17 H.O. LEUNG: No, I understand that. I'm
18 trying to balance the needs of the tribunal, the
19 opportunity to give you a full and a fair hearing and
20 to be respectful of the opportunity to expound as
21 much as you can, but I have to use my discretion
22 limited as much as I can.

23 MR. SIRI: Okay. The, the --

24 H.O. LEUNG: Can we move on to R11 and I'll
25 let you talk and tell me what this says.

1 MR. SIRI: So, R, R11 is this, this is an
2 example of a compensation of a hundred million
3 dollars that was given by the Vaccine Corp. for an
4 injury after the MMR vaccine and --

5 H.O. LEUNG: Thank you. Can we move on to
6 R12?

7 **[Respondent's Exhibit 11 admitted into**
8 **evidence.]**

9 MR. SIRI: I, I, -- the next one requires
10 me to ask questions in regards to antibiotics and what
11 this actually does in the body.

12 H.O. LEUNG: Tell me what R12 says first.

13 MR. SIRI: What I just gave you?

14 H.O. LEUNG: No, R12 the, the thing that's
15 coming.

16 MR. SIRI: Not everything I have has
17 exhibits. I'm only giving you exhibits that I have
18 but I have -- a lot of these are just questions to
19 elicit evidence from the witness. Most of what I was
20 going to do today regarding, regarding getting
21 evidence and in fact, I would think that would be
22 advantageous for them because it's their witness.

23 H.O. LEUNG: Okay. No, what I'm doing is
24 I'm --

25 MR. SIRI: And I'm not --

1 H.O. LEUNG: -- allowing you to produce
2 whatever evidence you want. I'm giving you a
3 sentence to comment what the evidence is.

4 H.O. LEUNG: Okay.

5 MR. SIRI: And I'm admitting it without
6 objection, okay. So, I'm giving you every
7 opportunity to put in --

8 MR. SIRI: Okay.

9 H.O. LEUNG: -- hundreds of pages of
10 documents. So, can we move on to R12?

11 MR. SIRI: Sure.

12 MS. PEONE: I need just one moment, Your
13 Honor --

14 H.O. LEUNG: Okay. Sure.

15 MS. PEONE: -- I apologize.

16 MR. SIRI: Exhibit 60.

17 [OFF MIC CONVERSATION]

18 H.O. LEUNG: Okay. Alright. Thank you.
19 Okay. Move on to R12.

20 MR. SIRI: So, what this is, is an
21 ingredient list for the vaccine and what you are
22 going to find is what's in this vial is that viruses
23 have to grow on something, okay. And they have a
24 growth medium that it needs to grow on. And so, you
25 know, each component -- so, the Measles, Mumps,

1 Rubella are each grown either on the embryo cell
2 cultured, human diploid lung fibroblast or fetal
3 bovine serum and actually most of what you have in
4 this vial is the actual growth medium that it's grown
5 on. So, you have components from chickens, from cows
6 as well as human diploid lung fibroblast, okay. That
7 -- those are from the cultured cell line of aborted
8 fetus. So, they take an aborted fetus, they took the
9 lung fibroblast, they culture it. It only -- it has
10 -- so, it dies out for generations and what they do
11 is they grow the Rubella virus on it. This vial
12 contains millions of millions of pieces of, of human
13 DNA in it, all broken down below 500 base pairs as
14 part of the manufacturing process. The whole point
15 of this vaccine is order to create antibodies. If
16 you are injecting it into the body, not only with the
17 viral components but the antigens from the human bo-,
18 bovine and chicken components, in particular, the
19 human components, it has the ability to create some
20 serious adverse events --

21 H.O. LEUNG: Understood.

22 MR. SIRI: -- relating to that.

23 H.O. LEUNG: We're going to move on the
24 R13.

25 **[Respondent's Exhibit 12 admitted into**

1 **evidence.]**

2 MR. SIRI: Okay. First, do you have
3 Exhibit 60? So, you -- so, you will see on the third
4 page that there is MMR and you can --

5 MS. PEONE: That's R12, 60 is already
6 entered?

7 MR. SIRI: Yeah. So, Exhibit 307 and
8 Exhibit 341 and 308. These are all document that use
9 the aborted fetal tissue and that is and that the
10 cell culture strain are still in this product that
11 you're looking at right now.

12 H.O. LEUNG: Okay.

13 MR. SIRI: And they want -- that, that they
14 want to inject into my client's body. And they --

15 H.O. LEUNG: This is the document?

16 MR. SIRI: This, this is the -- so, you can
17 match up WI38 and MRC5, those are the ingredients on
18 the exhibit. I don't know what it was marked, the
19 ingredient list for the vaccine. You can match up
20 with the --

21 H.O. LEUNG: I'm going to mark this as 13,
22 alright.

23 **[Respondent's Exhibit 13 admitted into**
24 **evidence.]**

25 MR. SIRI: Okay. And then Exhibit 341 says

1

--

2

H.O. LEUNG: This is 13. And you have R14

3

coming?

4

MR. SIRI: Exhibit 341.

5

H.O. LEUNG: Yeah.

6

MR. SIRI: And so, you know, when they

7

first licensed this vaccine, they didn't understand

8

the concept of the research from the genesis that,

9

that, that DNA below 500 page pair can readily insert

10

--

11

H.O. LEUNG: Counsel, can, can I, can I ask

12

you something?

13

MR. SIRI: Yeah.

14

H.O. LEUNG: And I'm going to ask you with

15

all due respect to -- without like in a professor

16

type thing educating me, just tell me in summary what

17

it says. I don't need the background, like, just

18

tell me what it purports to.

19

MR. SIRI: I'll try my best.

20

H.O. LEUNG: For instance, --

21

MR. SIRI: I'll try my best.

22

H.O. LEUNG: R12 or whatever you just said.

23

MR. SIRI: I'll try my best to give you

24

what you're asking for --

25

H.O. LEUNG: I understand you.

1 MR. SIRI: -- despite the fact that it's
2 missing critical pieces to understand --

3 H.O. LEUNG: I understand.

4 MR. SIRI: -- how the connected tissue.
5 So, I'm not sure what you're, you know, --

6 H.O. LEUNG: So, what is R14, tell me?

7 MR. SIRI: You know, so, well, well, so,
8 R14 and R15 those are the product descriptions for
9 what's on the ingredient list.

10 H.O. LEUNG: That's all I needed to know.
11 Thank you.

12 **[Respondent's Exhibits 14 and 15 admitted**
13 **into evidence.]**

14 MR. SIRI: Okay. That's what I was telling
15 you.

16 H.O. LEUNG: Okay.

17 MR. SIRI: Okay. And then R --

18 H.O. LEUNG: And then we have R16?

19 MR. SIRI: R -- yeah, Exhibit 341.

20 MS. PEONE: That's R15.

21 MR. SIRI: 341, I don't know what your R
22 are up to.

23 MR. MERRILL: Yeah, this one that we have,
24 R15.

25 MR. SIRI: Yeah, yeah, okay. So, that's,

1 that's, you know, that's a history of the use of the,
2 the tissue. Can I, can I get Ex-, Ex-, Exhibit 70,
3 please? This was a -- this was one of the, the
4 seminal studies, this was done with, you know, 80
5 aborted fetuses in order to create the Rubella
6 component where they take the fetus so they, they
7 come to three centimeter tubes every --

8 H.O. LEUNG: I am going to mark that as
9 R16.

10 **[Respondent's Exhibit 16 admitted into**
11 **evidence.]**

12 MR. SIRI: -- component of the body --

13 H.O. LEUNG: Yes.

14 MR. SIRI: -- into the lungs and so forth
15 and they culture it to see it's good for vaccine
16 production. And then, let me just skip ahead here to
17 Exhibit 321. And so Exhibit 321 is, is -- this is,
18 this is somebody work for major genetics companies in
19 Silicon Valley. She -- and, and so she's got a
20 letter regarding the use of fetal DNA in the MMR
21 vaccine and the issues related thereto. Can I get
22 Exhibit 267? Now, you know, measles has been around
23 since the beginning of recording history as far as I
24 understand. It's something that's actually part of
25 nature or God, whatever one wants to call it, okay.

1 But the MMR is not. MMR is a man made product, okay.
2 It's something that's only come about because of
3 man's creation. And so, you know, there might have
4 been a reason that the measles vaccine is part of the
5 natural world as we know it. What this is, is
6 handing you is a, is a prospect, the study of a
7 100,000 individuals in Japan that were followed for
8 22 years by the major health authorities and what
9 they found is that those had gotten measles and
10 mumps, okay. Those have got measles and mumps, 95
11 percent of them were still alive, didn't die from
12 cardiovascular disease after 22 years. But of those
13 that didn't have measles and mumps, okay, only 85
14 percent of them survived. That's a huge
15 differential. And that is from major peer review
16 study by major institutions. What it shows is that
17 getting measles and mumps potentially, let me get the
18 next Exhibit 309, getting measles and mumps, the
19 study indicates it actually protects you from
20 cardiovascular death. Cardiovascular disease killed
21 600,000 Americans last year. The measles killed 4-,
22 around 400 Americans a year in a few years before the
23 measles vaccine was first licensed in 1963, okay.
24 So, if, if the measles -- if eliminating measles
25 cause 5 percent of cardiovascular deaths, that far

1 outnumbers the number of death from actual measles.
2 You have 309? That is the -- that's the number of
3 deaths from heart disease. And that study, as far as
4 that study remains un-rebutted in the medical
5 literature. There is nothing that contradicts that
6 finding.

7 H.O. LEUNG: That's R19, Counsel is
8 referring to?

9 MR. SIRI: Yeah.

10 **[Respondent's Exhibits 17 to 19 admitted**
11 **into evidence.]**

12 MS. PEONE: Yes.

13 MR. SIRI: Okay. Now, there is also
14 numerous, numerous studies that show that those who
15 had measles have far less rates of various cancers.
16 Can I please have Exhibit 265? Okay. So, this is,
17 this is a study out of the International Agents for
18 Research on Cancer in Lyon, France, okay. And what
19 they found is that those who had measles had a 60-
20 that those who did not have measles had a 66 percent
21 increase rate of non Hodgkin's Lymphoma and a 233
22 percent increase rate of Hodgkin's Lymphoma.

23 H.O. LEUNG: That's R20?

24 **[Respondent's Exhibit 20 admitted into**
25 **evidence.]**

1 MR. SIRI: That's R20 and that one also
2 remains un-rebutted in the medical literature as far
3 as we are aware. Can I get Exhibits 310, 311 and
4 Exhibits 330? These are all studies consistently
5 showing peer review science that those who have
6 measles have far less rates of various cancer
7 including ovarian cancers and, and, and Exhibit 335.
8 And I'm also going to provide you the number of
9 people that died from, from non-Hodgkin's Lymphoma.
10 That's 20,000 people last year. A percentage of that
11 relates to people not getting measles. You can just
12 do the math. 400 deaths from measles in the years
13 before 1963, that's according to the CDC versus how
14 many people have died because you have eliminated
15 measles. And people who want to exercise their right
16 to not get this vaccine --

17 H.O. LEUNG: That's R21.

18 MR. SIRI: Okay.

19 H.O. LEUNG: Admitted.

20 **[Respondent's Exhibit 21 admitted into**
21 **evidence.]**

22 MR. SIRI: Which, which one are you --

23 H.O. LEUNG: Fever and infectious child
24 diseases in history of cancer patients and that it
25 controls.

1 MR. SIRI: So, one of those actually was
2 about ovarian cancer which kills 13,000 people a year
3 in the United States. It showed that having measles
4 have, have a risk of having ovarian cancer.

5 H.O. LEUNG: R22 appears to be a --

6 MR. SIRI: I just want to make something --

7 [CROSSTALK]

8 MR. SIRI: I want to make something very
9 clear for the record. I'm not testifying today. I
10 am, I am telling you -- these are, these are
11 documents and, you know, the, the evidence testifies.

12 H.O. LEUNG: Exactly.

13 MR. SIRI: So, the -- these documents --

14 H.O. LEUNG: Okay.

15 MR. SIRI: -- speak meaning and I'm trying
16 to fill in the gaps for you but I'm not a, I'm not a,
17 I'm not a witness. I was intending --

18 H.O. LEUNG: Right.

19 MR. SIRI: -- to create the connected
20 tissue through their own witness but I've not --

21 H.O. LEUNG: Yeah. Well, let me just say
22 something, Mr. Siri.

23 MR. SIRI: Okay. 312 --

24 H.O. LEUNG: In OATH hearings, an attorney
25 statements when, when it did come in, it is testimony

1 to the extent that you are introducing these
2 documents. And you can testify --

3 MR. SIRI: Okay.

4 H.O. LEUNG: -- in place of your client.
5 You can testify in place of the client's doctor. You
6 can testify -- triple hearsay is permitted. Whatever
7 you need to say, I'm taking into consideration.
8 Everything is testimony, okay.

9 MR. SIRI: Triple hearsay?

10 H.O. LEUNG: Triple hearsay.

11 MR. SIRI: What about quadruple?

12 H.O. LEUNG: Yeah, everything is admitted,
13 very informing.

14 MR. SIRI: Okay.

15 H.O. LEUNG: R23 is admitted, R24 is
16 admitted. Everything from R7 upwards that we have
17 admitted. We are now up to R24 has been admitted
18 without objection.

19 **[Respondent's Exhibits 22 to 24 admitted**
20 **into evidence.]**

21 MR. SIRI: Okay. Let me just confirm that
22 we get -- so we did, we did all of these.

23 MS. PEONE: And we have 311, 310, 330.

24 MR. SIRI: 335.

25 MS. PEONE: 335.

1 MR. SIRI: 266 -- and 266.

2 MS. PEONE: 266.

3 MR. SIRI: Okay. This is -- you're being -
4 - this is you're being handed a survey from the
5 Department of the Healthcare and the epidemiology at
6 the University of British Columbia again documenting
7 differentials.

8 H.O. LEUNG: Okay. R25 is admitted.

9 **[Respondent's Exhibit 25 admitted into**
10 **evidence.]**

11 MR. SIRI: So, between those that have had
12 measles and those that have not had measles.

13 H.O. LEUNG: Okay. Is this the last of the
14 documents, Counsel?

15 MR. SIRI: No, almost. 312 is --

16 H.O. LEUNG: Okay. Let's move on.

17 MR. SIRI: -- that gives you the number of
18 deaths from ovarian cancer per year.

19 H.O. LEUNG: Okay.

20 **[Respondent's Exhibit 26 admitted into**
21 **evidence.]**

22 MR. SIRI: So, you can have a comparative
23 study. There are various -- I don't know how to do
24 this [unintelligible] [02:30:43], but basically the
25 doctor could explain this but we're not going to do

1 that. Essentially, bottom line is that -- alright,
2 let's just leave it alone. Let me get that --

3 H.O. LEUNG: R26 in a minute?

4 MR. SIRI: 329. These, these three, okay.
5 So, these are studies that show that children who
6 have had measles have far less allerg-, allergies and
7 atopic diseases. Atopic diseases are things like
8 asthma. It's when you're sensitized to something in
9 the environment. So, children that have had, that
10 have had measles have far less of these conditions.

11 H.O. LEUNG: That's R27? It's admitted.

12 **[Respondent's Exhibits 27 admitted into**
13 **evidence.]**

14 MR. SIRI: That's three of those, 329, 336
15 and -- 329 and 336. Just, just do those two, we
16 don't need to use the other one, two is enough.

17 H.O. LEUNG: That's going to be R28.

18 **[Respondent's Exhibit 28 admitted into**
19 **evidence.]**

20 MR. SIRI: Okay. And then Exhibit 331, 331
21 is the study that actually looked at Parkinson's rate
22 in adulthood between those who have had measles and
23 those who don't. Those who have had measles have the
24 rate of Parkinson's disease.

25 H.O. LEUNG: Okay.

1 MR. SIRI: You know, you know, when you,
2 when you looked at the world, my clients believe that
3 God created the world, that there is a divine
4 creator. There might have been a reason that God
5 created the world the way he did. They want to just
6 exist in this world the way God created it. I think
7 all of these peer reviewed science that I don't know
8 any studies, we're not aware of any study that rebut
9 these findings. Hence, this is the best available
10 evidence --

11 H.O. LEUNG: R29 is admitted.

12 **[Respondent's Exhibit 29 admitted into**
13 **evidence.]**

14 MR. SIRI: -- about what [unintelligible]
15 [02:32:21] measles does shows -- supports that, that
16 you've -- on the four prongs we talked about,
17 fairness, justice, medically appropriate, is it
18 medically appropriate to increase a child's risk of
19 cancer, atopic disease, heart disease in order to
20 prevent them from having what's typically been
21 considered a, a mild childhood illness.

22 H.O. LEUNG: Is this the end of the
23 document?

24 MR. SIRI: Almost. So, Exhibit twe-, let
25 me get Exhibit 20. So, Exhibit 20 is the, is the, is

1 the package insert for MMR, the MMR vaccine itself.
2 So, this is from the manufacturer. You can see in
3 there that despite having millions of pieces of DNA,
4 it's never been evaluated for whether you can call it
5 mutate genes. Let me get Exhibit 3 --

6 H.O. LEUNG: That's Respondent 30 admitted
7 without objection.

8 **[Respondent's Exhibit 30 admitted into**
9 **evidence.]**

10 MR. SIRI: Yeah, Exhibit 313. This is the
11 study out of Canada from their health authorities and
12 what they did is they tracked what happ-, within two
13 weeks of getting MMR, how many kids went to the
14 emergency room that wouldn't have otherwise went.
15 One in a 168 children ended up in the emergency room
16 according to the Canadian health researchers, that
17 wouldn't have otherwise ended up there because they
18 received the MMR vaccines, pretty recent study, still
19 waiting for an HHS response on that one. It's quite
20 a concerning finding but obviously that's, you know,
21 an issue in Vaccine Corp. Because, you know, my firm
22 that does vaccine injury cases in Vaccine Corp, we
23 have studies from ACDC or FDA or HHS that shows that
24 vaccine causes harm, they are going to be liable
25 because they are the respondent in the vaccine injury

1 compensation program. It's part of the Federal Court
2 of Claims. You can go to the Federal Court of Claims
3 website anytime, click on vaccine claims and you can
4 read all about the vaccine injury compensation
5 program down in Washington DC that's administered in
6 the Federal Court of Claims in a specialized program.
7 There is no discovery and you have to give all your
8 evidence and, and, and, and the government is
9 offended by this little law firm called the
10 Department of Justice. Just like there are
11 government attorneys here defending vaccines, there
12 are government attorneys defending on the federal
13 level too. Do we do Exhibit -- what do we have?

14 **[Respondent's Exhibit 31 admitted into**
15 **evidence.]**

16 MS. PEONE: 313.

17 MR. SIRI: Okay. We did 313? Okay. You
18 know, and Exhibit 20 just, just point out that it has
19 a long list of, of adverse reactions. I'm just going
20 to read 21CFR, it's one sentence, 201.57C7 and what
21 the Code of Federal Regulation provides is that on
22 the package insert, despite popular belief, the only
23 adverse reactions that are supposed to be listed that
24 are, that are post marketing are, "Only those adverse
25 events for which there are some basis to believe

1 there is a causal relationship between the drug and
2 the occurrence to the adverse event". That's the
3 Code of Federal Regulations. When you see adverse
4 events on the MMR package insert, the only reason
5 it's there is because the manufacturer had a basis to
6 believe there is a causally related but they are not
7 liable. So they, you know, they pop it on there and
8 who knows what their evidence is because you can't do
9 discovery.

10 **[Respondent's Exhibit 32 admitted into**
11 **evidence.]**

12 H.O. LEUNG: Are we done with the
13 documents, Counsel?

14 MR. SIRI: Twenty two and 21. These are
15 example of a Merck amending their package insert to
16 add Transverse Myelitis in 2014 and, and, and another
17 I think, another serious injury in 2017, of course,
18 getting discovery as to the evidence that supported
19 that, you, you can't get because you can't sue them
20 for the injuries. You can get, you know, hundreds of
21 millions of dollars for robocall violations but you
22 can't a dollar pretty much out of Merck unless it can
23 be proffered if a child dies from MMR vaccine. Let
24 me get Exhibit Number 53. So, there is actually only
25 one study that I am aware of that looked at the

1 health outcomes of the vaccinated and non-vaccinated
2 children in the United States. It was a small study.
3 It could be far better but it's the only one. It's
4 Exhibit 53 and what it found was there is lots of,
5 you know, lots of the issues and concerns that the
6 IOM looked at, that are in the package insert that
7 study found it was out of the school public health of
8 Jackson University were increased. You know, the
9 question is one of, are you trading, avoiding a
10 limited, limited infection for a chronic health
11 issue. Okay. Moving on, moving on --

12 **[Respondent's Exhibits 33 and 34 admitted**
13 **into evidence.]**

14 H.O. LEUNG: So, I'm going to, I'm going to
15 ask you to document how many more you have.

16 MR. SIRI: Exhibit 16.

17 H.O. LEUNG: How many more do you have
18 approximately?

19 MR. SIRI: No, I have only got several
20 pages so we went through -- we are on Page 19. I
21 have few more pages so not much, okay. Exhibit --
22 which one did we just do?

23 MS. PEONE: This is 16.

24 MR. SIRI: Exhibit 16.

25 MS. PEONE: I'm so sorry, 34

1 H.O. LEUNG: Thirty four, yeah.

2 MR. SIRI: We, we just did 34? No, 53.

3 MS. PEONE: We are on Exhibit Number 16.

4 MR. SIRI: Right, but which one did we --
5 okay, because --

6 H.O. LEUNG: We just did this one.

7 MR. SIRI: We just did that? Okay. So,
8 you know, this, this is a report by the Congress with
9 regards to, you know, ACIP that we talked about
10 earlier. ACIP makes the vaccine recommendations
11 including adding the MMR. And what Congress found is
12 that most of those people who sit on that ACIP Board
13 have conflicts with pharmaceutical companies. You
14 can read it. It's wonderful interesting read.
15 Exhibit 238, please. Okay. And what you can find
16 here is that the CDC vaccine schedule from 2000 which
17 is the same year that this report was issued. It was
18 on the schedule by that point. Let me get Exhibit
19 16. Well, we already did 16, okay. Let, let, let's
20 move on to Exhibit 2-, 272. So, you know,
21 understanding that pharmaceutical companies in this -
22 - I think I'm done in like five, 10 minutes total.

23 H.O. LEUNG: What, what I'm going to do
24 Counsel, is I'm going to --

25 MR. SIRI: I'm, I'm --

1 H.O. LEUNG: -- let you introduce whatever
2 documents you have and I'm going to let the title of
3 those documents --

4 MR. SIRI: I'm going as fast as I can.

5 H.O. LEUNG: No, no, no, you can summarize
6 what's coming.

7 MR. SIRI: I am.

8 H.O. LEUNG: You don't have to --

9 MR. SIRI: I'm not, I'm not slowing this
10 down.

11 H.O. LEUNG: No, no, just tell me that --

12 MR. SIRI: The only thing slowing down is
13 having this discussion.

14 H.O. LEUNG: -- tell me the titles of the
15 documents that's coming in.

16 MR. SIRI: Okay. This, this is Exhibit --
17 this is the mandate for safer child vaccine which is
18 a part of the 1986 act, codified in United States
19 code. It's what underpins vaccine safety in this
20 country. You can see the title right there. It's,
21 it -- what it does is it requires and, and you can
22 see these are titles. It has a general rule. It has
23 a task force. It has a report that is submitted
24 every two years to Congress in which HHS documents
25 how they made vaccines safer, okay. Exhibit 273, you

1 might just leave this out, and cover it up as we go
2 through the next two because it's going to be
3 relevant. Essentially, because vaccine, vaccine
4 manufacturers are immunity from liability, this is
5 what underpins vaccine safety. HHS is assuring their
6 safety. You could see it under Provision 1. And so
7 every year, the cong-, the HHS submitted by the end
8 of year a report to Congress. This is a stipulation
9 from Federal Court and what you'll find is that these
10 reports required by Section C every year, have never
11 been submitted a single time. This was a stipulated
12 order in Federal Court showing they've never actually
13 done that and that's a simple requirement, just
14 submit a report. Exhibit 274, please And then for
15 the task force, if you recall under the neck, the
16 title, okay, this is the task force for safe-, and
17 this document right here. The task force for safer
18 childhood vaccines, okay. This task force was to
19 make recommendations on how to make vaccine safer to
20 the secretary of HHS and this is a response to a
21 [unintelligible] [02:38:58] request and you'll see,
22 that task force was dissolved in 1998. It doesn't
23 even exist. They are not doing even a simple task
24 required to show the MMR vaccine is safe. Let me get
25 Exhibit 318 and 319, okay. This is, this is a group

1 of physicians and that's -- that, that have compiled,
2 you know, a summary of the risks of the MMR vaccine
3 and, and so forth. You know, these are physicians so
4 they are writing it from the perspective of
5 physicians.

6 H.O. LEUNG: Counsel?

7 MR. SIRI: And those positions. 319 and
8 318 --

9 H.O. LEUNG: I'm going to stop you right
10 there. I'm going to stop you right there.

11 MR. SIRI: Yeah.

12 H.O. LEUNG: Just let me stop you.

13 MR. SIRI: Sure.

14 H.O. LEUNG: I'll just put on the record.
15 We've been on the record for close to --

16 MR. SIRI: Exhibit 146.

17 H.O. LEUNG: Hold on, Counsel, two hours
18 and 40 minutes now.

19 MR. SIRI: Yeah.

20 H.O. LEUNG: You have documents to tend to
21 show that the --

22 MR. SIRI: Exhibit 146.

23 H.O. LEUNG: We have admitted 39 documents
24 consisting of probably over 600 pages. Counsel,
25 stop.

1 MR. SIRI: Yeah.

2 H.O. LEUNG: Stop, stop, stop. Okay. To
3 the extent that you have further documents to support
4 your proposition that this summons should not have
5 been issued and it's unjust to issue it, I'm going to
6 allow you to admit that and mark it.

7 MR. SIRI: Okay. One second.

8 H.O. LEUNG: The next one to be 40 and I'm
9 going to let you mark it and your, your assistant
10 mark it from 40 onward. When it's marked and
11 everything is ready to be admitted, let me know.
12 Right now, we're going to -- I'm going to allow both
13 sides to go to the substance. Is there anything you
14 want to argue in terms of summation because I'm
15 moving to that right now? Is there anything else,
16 after you present this evidence, is there any other
17 testimony you want to provide that's relevant to the
18 issues in, in, in the summons?

19 MR. SIRI: Yeah, can I just give direction
20 as to what exhibits to be marked, please?

21 H.O. LEUNG: Sure, sure.

22 MR. SIRI: So, I'm going to circle the ones
23 that I'd like to mark.

24 H.O. LEUNG: Just hold it into the
25 [unintelligible] [02:40:37] and then I am going to

1 read it all in mass, okay? Thank you. The documents
2 that I've admitted so far --

3 MR. SIRI: Almost done.

4 H.O. LEUNG: -- only up to Respondent's 39,
5 Department of Health, any objection to those being
6 admitted into evidence?

7 MR. MERRILL: No objection.

8 H.O. LEUNG: Okay. They are admitted into
9 evidence.

10 **[Respondent's Exhibits 35 to 39 admitted**
11 **into evidence.]**

12 MR. SIRI: Okay. So, just this is 1, 2, 3,
13 4, 5, 6, okay. And so, you know, between 1900 and
14 1962, okay, when there was absolutely no measles --

15 H.O. LEUNG: Counsel, I'm going to stop you
16 because I understand your argument --

17 MR. SIRI: Because you said summation.

18 H.O. LEUNG: Yeah, I am --

19 MR. SIRI: Summing.

20 H.O. LEUNG: You're summing up?

21 MR. SIRI: Summing.

22 H.O. LEUNG: Go ahead.

23 MR. SIRI: You told me to sum, I figured
24 you are giving me --

25 H.O. LEUNG: Go ahead.

1 MR. SIRI: -- three sentences.

2 H.O. LEUNG: Go ahead.

3 MR. MERRILL: Do I get to put a couple of
4 things in --

5 H.O. LEUNG: Sure.

6 MR. MERRILL: Okay.

7 H.O. LEUNG: Before we do the sum up, I'm
8 going to turn to Department of Health. You had about
9 a couple of hours [unintelligible] [02:41:39].

10 MR. MERRILL: Okay. First of all, I just
11 want to add one more document, Your Honor. This is
12 the frequently asked questions of those who are
13 handed up -- were served on the, all the respondents
14 which gives instructions on how to submit medical
15 proof. I also have a --

16 H.O. LEUNG: This is a multi paged document
17 that I'm going to enter -- mark as P --

18 [OFF MIC CONVERSATION]

19 H.O. LEUNG: I think we have 3, don't we?

20 No?

21 MR. MERRILL: I thought we were on 2.

22 H.O. LEUNG: Two? Okay. I'm going to mark
23 it as P3.

24 MR. MERRILL: Okay.

25 H.O. LEUNG: It's a document entitled

1 frequently asked questions, New York City measles
2 Vaccine Order zip codes 11205, 11206, 11211 and
3 11249.

4 MR. SIRI: Can I see a copy of what you are
5 submitting?

6 H.O. LEUNG: I'm handing it to counsel to
7 look at.

8 MR. SIRI: Yeah, my --

9 H.O. LEUNG: Any objection to that being
10 admitted into evidence?

11 MR. SIRI: My only objection is I don't
12 have an opportunity to cross examine the Department
13 of Health about it.

14 H.O. LEUNG: You can ask him questions
15 about it. What -- you are here representing, Mr.
16 Siri. You have a question about it?

17 MR. MERRILL: It actually came up in the
18 testimony. We already answered his questions here
19 but --

20 H.O. LEUNG: Okay. Do you have any
21 questions for the Department of Health, Counsel, on
22 these -- on this document? First of all, you, you
23 don't object P3 is admitted into evidence.

24 MR. SIRI: Right, my objection is what it
25 was.

1 H.O. LEUNG: Yeah.

2 MR. SIRI: Yeah, you know, this, this
3 document also says the vaccine is safe and I think
4 it, it implies that the benefits outweigh the risks -
5 -

6 H.O. LEUNG: Got you. I understand so --

7 MR. SIRI: And, and, and --

8 H.O. LEUNG: I'm going to take your
9 testimony --

10 MR. SIRI: Yeah.

11 H.O. LEUNG: -- that you disagree with the
12 assertions in it.

13 MR. SIRI: So, can I -- so, can I ask about
14 the substance of this document? There is lots of
15 things in here.

16 H.O. LEUNG: What do you mean by asking
17 about the substance? What are you talking about?

18 MR. SIRI: Well, you know, there is lots of
19 assertions in this document that --

20 H.O. LEUNG: You can, you can -- you don't
21 have to ask questions. You can, you can rebut the
22 assertions based on your testimony. You can say --

23 MR. SIRI: Yeah.

24 H.O. LEUNG: -- look, Paragraph 3, I
25 disagree with it, just --

1 MR. SIRI: Yeah. Well, okay. So, for
2 example, the Health Department has set multiple
3 strategies on the outbreak. Now, what they did is in
4 the Jewish community, when there were cases, they
5 excluded the children from school, okay. And they
6 did that back in 2000-, in 2018, okay. Using that
7 heavy handed approach, for months, there were not
8 that many cases. What they did is they laughed at
9 those people you have that firm belief about this
10 injecting this product with only two options. They
11 either have to give a product that was against their
12 conscience to do that in a way they lived 1000 years
13 or they had to get their child have measles to go
14 back to school. And so, --

15 H.O. LEUNG: Counsel, I think this is in
16 support of your summation that this should not have
17 been issued. So, I'm just asking --

18 MR. SIRI: Well, it's directly related to
19 what's been argue in here.

20 H.O. LEUNG: Okay.

21 MR. SIRI: Because it says in here. It
22 says, you know, they, they tried and, and so what
23 they are, what -- I mean, I would do this through
24 that you said I should just summarize it. So, the
25 point is, is that, what it did is that, this was not

1 an -- it wasn't an outbreak in the traditional sense.
2 Epidemiologically, it didn't follow that trend. What
3 it was it that it became a spi-, when
4 [unintelligible] [02:44:09] they had measles parties
5 as the Commissioner of Health had said. Measles
6 parties, that why it didn't go outside of the Jewish
7 community. People were trying to get their kids back
8 in school and it was the heavy hand in the Jewish
9 community that did this. There were cases that were
10 in public schools where they didn't exclude the
11 unvaccinated kids in those schools.

12 H.O. LEUNG: The P3 is --

13 MR. SIRI: I, I had more point, okay.

14 H.O. LEUNG: Alright. So, P3 is admitted.

15 **[Petitioner's Exhibit P3 admitted into**
16 **evidence.]**

17 MR. MERRILL: Your Honor, it's being
18 admitted to the party that there was a lot of
19 testimony earlier about, you know, where people told
20 that they could, could submit medical objections and
21 proof of immunity and that's, that's why it brings --

22 H.O. LEUNG: Okay. Was P3 provide --
23 provided to Respondent?

24 MR. MERRILL: Yes, it was given, she had
25 given it.

1 H.O. LEUNG: Okay.

2 MR. SIRI: With --

3 H.O. LEUNG: Okay. I also want --

4 MR. SIRI: With the violation.

5 MR. MERRILL: I also want, I also want to
6 mark as P -- yes, and that was correct the witness
7 had provided. I also want to mark in -- there's been
8 a lot of statutes and other things submitted. So, I
9 want to submit a copy of that Judge Pels [phonetic]
10 decision which upheld the order back in April and so
11 I have a copy for you, Your Honor.

12 MR. SIRI: Thank you.

13 MR. MERRILL: And I, I think the witness
14 was pointing out that the safety and efficacy of the
15 vaccine was brought in that case as well. And if you
16 look at the decision whether his doctor is testifying
17 it, they had actually had [unintelligible] [02:45:15]
18 the doctor had submitted affidavits. The Plaintiff's
19 expert there, [unintelligible] [02:45:19] cited that
20 there is very little mainstream scientific evidence
21 about being --

22 MR. SIRI: I, I submit for the record that
23 -- okay.

24 [CROSSTALK]

25 H.O. LEUNG: I'll mark it as P4. So, any

1 objection to this decision being admitted?

2 MR. SIRI: Well, it's just the
3 characterization, number one, it only addresses the -
4 -

5 MR. MERRILL: According, according from
6 that -- according to --

7 MR. SIRI: Yeah, it only -- it only, it
8 only address one of the constitutional arguments that
9 I have raised, not, not the [unintelligible]
10 [02:45:37] and, and, and, and --

11 MR. MERRILL: I just want to raise, we've
12 accepted a lot of hearsays and a lot studies, you
13 know, about, about the data that you pointed out but
14 the doctors has testified to [unintelligible]
15 [02:45:45] in there [unintelligible] [02:45:46].

16 MR. SIRI: Those doctors are not here
17 today. I didn't bring them in my case. I brought
18 evidence from the Institute of Medicine, the FDA, the
19 CDC.

20 MR. MERRILL: You put, you put it in
21 letters -- you put in letters --

22 H.O. LEUNG: Alright. Alright.

23 MR. SIRI: So, these -- most of the
24 evidence been --

25 H.O. LEUNG: Counsel, Counsel --

1 MR. SIRI: Yeah.

2 MR. MERRILL: Okay.

3 H.O. LEUNG: Let, let's give him a chance
4 to talk.

5 MR. SIRI: I was responding to his --

6 H.O. LEUNG: I understand.

7 MR. SIRI: I wasn't. He cut me off.

8 H.O. LEUNG: I understand.

9 MR. SIRI: I was responding.

10 MR. MERRILL: I didn't cut you off. You
11 cut me off right now.

12 H.O. LEUNG: Okay.

13 MR. MERRILL: I let you go for hours to put
14 in letters and put in like, --

15 H.O. LEUNG: Alright. Alright.

16 MR. MERRILL: -- you know, and then lastly,
17 Your Honor, I just want to read from, I think it's
18 Respondent's 2. This is the key statement that were
19 in context here which has been grossly distorted.

20 H.O. LEUNG: Respondent's 2?

21 MR. MERRILL: Yeah.

22 H.O. LEUNG: Okay. Let me take a look.

23 MR. MERRILL: If you look there, it talks
24 about Section 4, it's Page 2 risk of vaccine
25 reaction. I just want to say that in, in, in the

1 document the Plaintiff had put in --

2 MR. SIRI: I thought the document speak for
3 itself.

4 MR. MERRILL: -- getting MM-, well -- you -
5 - getting MMR vaccine is much safer than getting
6 measles, mumps or Rubella disease. And then going
7 down at the bottom where it talks about the risk, and
8 the severe allergic reaction, we don't know, we have
9 testimony about that. It says any medication can
10 cause a severe allergic reaction, such reactions to
11 vaccine are estimated to be about one in one million
12 doses.

13 MR. SIRI: That is for only for
14 anaphylaxis, not for brain damage, not for coma --

15 MR. MERRILL: Now, that's the severity --

16 MR. SIRI: -- not for seizures, that's not
17 for any of those --

18 H.O. LEUNG: Okay.

19 MR. SIRI: -- that's a comp-, that is not
20 what it, that's not what it says and severe and rare
21 means one in a thousand, one in a thousand.

22 H.O. LEUNG: Understood, understood both
23 sides' argument. Do you have any objection to the
24 decisions that's marked P4 being admitted into
25 evidence?

1 MR. SIRI: This -- but -- I don't have an
2 object-, it's a, it's a decision. I have no
3 objection to it being admitted. I just want to say -
4 -

5 H.O. LEUNG: That's for me to consider.

6 MR. SIRI: -- once --

7 H.O. LEUNG: Because it's -- if it's in
8 evidence, I will consider it. Do you any objection
9 to me considering this in my decision?

10 MR. SIRI: Well, I have, I have -- yes, I
11 object to it be considered in anyway --

12 H.O. LEUNG: Okay. P4.

13 MR. SIRI: -- anything in there is fact --

14 H.O. LEUNG: Four is admitted into evidence
15 and you're going to --

16 **[Petitioner's Exhibit P4 admitted into**
17 **evidence.]**

18 MR. SIRI: -- as fact --

19 H.O. LEUNG: Okay.

20 MR. SIRI: I object to you considering
21 assertions in there as factual.

22 H.O. LEUNG: Got you.

23 MR. SIRI: It's a legal decision.

24 H.O. LEUNG: Okay. Hold on.

25 MR. SIRI: The facts --

1 H.O. LEUNG: Understood.

2 MR. SIRI: -- it's not in evidence.

3 H.O. LEUNG: Understood.

4 MR. SIRI: Is what I'm, is my -- yeah, I,
5 I, that's --

6 H.O. LEUNG: Understood.

7 MR. SIRI: And, and the characterization --

8 H.O. LEUNG: Hold on one second before you
9 go further.

10 MR. SIRI: Okay.

11 H.O. LEUNG: Because I'm going to give you
12 an opportunity. I promise you I'm going to give you
13 an opportunity.

14 MR. SIRI: Okay.

15 H.O. LEUNG: But you, you spoke at length
16 and I want to give Department of Health, Mr. Merrill
17 an opportunity to address all the issues that they
18 have. Have you completed? Is there anything else
19 you want to add? Okay. Now that that's done, I'm
20 going to ask, do you have anything you want to
21 testify to? Anything of substance you want to tell
22 me?

23 MR. SIRI: Of?

24 H.O. LEUNG: About the case, about why we
25 are here for.

1 MR. SIRI: Well, I, I, you know, I, I -- do
2 you want to just -- are we just going to rest on this
3 record because --

4 MS. PEONE: No, we don't have to rest.
5 First --

6 MR. SIRI: -- the rec-, look --

7 H.O. LEUNG: First thing we're going to do
8 is --

9 MR. SIRI: -- the record, the record is --
10 listen, the record -- well, let's get these in. You
11 know, I, I just -- I mean, I'll, I'll -- I want to --
12 I'll -- my summation is as to the four arguments, the
13 four core arguments, I don't believe, I mean, I just
14 stand on my objection about not, you know, being able
15 to make a fulsome record. Separate from that, I'm
16 happy, you know, I think that the arguments that we
17 made on the first point speaks for themselves. I'm
18 happy to rest on the record here today if Mr. Merrill
19 is as well.

20 H.O. LEUNG: Okay. Okay. So, there is
21 nothing further either side needs to address. Is
22 that correct?

23 MR. MERRILL: Right.

24 H.O. LEUNG: Okay.

25 MR. SIRI: As long as your, as long as you

1 -- as long as your objection stand, then no.

2 H.O. LEUNG: You mean your objection,
3 right?

4 MR. SIRI: Yeah. I, what -- I apolo-,
5 you're -- right. You're, you're limiting rulings
6 that I objected to.

7 H.O. LEUNG: Right. Okay. I have enough
8 to make a decision. I'm going to take the case under
9 advisement and issue a written decision. You will
10 receive within 30 days. Hearing nothing further from
11 either parties, this hearing is adjourned. The
12 record should reflect that the extensive arguments
13 that form the basis of --

14 MR. SIRI: Wait, did we finish putting the
15 rest in? I'm sorry.

16 H.O. LEUNG: I'm going to do it right now.

17 MR. SIRI: Okay.

18 H.O. LEUNG: The extensive arguments made
19 at the later portion of this hearing applies to
20 subsequent summons that we are going to either hear
21 today or be adjourned at a later date if we run out
22 of time. Mr. Siri has indicated that the substantive
23 arguments that has taken up the majority of the
24 nearly three hours hearing is a common, is a common
25 defense to the subsequent summons -- summonses that

1 we're going to hear. So, to the extent that the
2 subsequent summonses will refer to the record here,
3 it will be to save time so that all the arguments
4 that we -- that took up over two hours will not have
5 to be repeated. So, this record will be joining the
6 other records. The record should reflect that I've
7 also admitted the following documents. We ended at
8 R39. We have now gone to R40, R41, R42, R43, R44 and
9 R45. And I've given a chance to DOH to review that,
10 any objection going up to R45?

11 MR. MERRILL: No, Your Honor.

12 H.O. LEUNG: Hearing no objection, these
13 are admitted into evidence and hearing nothing
14 further from either parties, is that correct?

15 **[Respondent's Exhibits 40 to 45 admitted**
16 **into evidence.]**

17 MR. MERRILL: Correct.

18 H.O. LEUNG: This hearing is conclu-,
19 conduct-, concluded, thank you.

20 [END OF HEARING]
21

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health & Mental Hygiene v. Malky Tabak on August 28, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By



Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018

SUMMONS NUMBER: 30198-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE
DIVISION: Disease Control BUREAU: Immunization
AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Malky Tabak ID NUMBER: 50091595

ADDRESS: 585 Marcy Avenue APT# 2E, Brooklyn, 11206 PHONE: _____

DATE AND TIME OF OCCURRENCE: April 21, 2019, 09:00 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 585 Marcy Avenue APT# 2E, Brooklyn, 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 6, 2019 AT: 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

Manhattan 66 John Street 10 th & 11 th Floor New York, NY 10038	Staten Island 390 St. Marks Place Main Floor Staten Island, NY 10301	Bronx 3030 Third Avenue Room 250 Bronx, NY 10455	Queens 31-00 47 th Avenue 3 rd & 4 th Floor Long Island City, NY 11435	XX Brooklyn 9 Bond Street 6 th & 7 th Floor Brooklyn, NY 11201
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INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be denied against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, C.R., who is at least six months old, lives at: 585 Marcy Avenue APT# 2E, Brooklyn, 11206, which is located in one of the affected zip codes listed in the Order. On April 21, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child C.R. has no record of measles immunization. Respondent has failed to vaccinate child C.R. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 2048 and 2049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice.

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to Section 210.45 of the Penal Law.

Deborah Kaplan Deborah Kaplan Signature 4/23/19 Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by: _____

Print Name	Signature	Title	Date:
<p>The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.</p>			
<p>If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.</p> <p>If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.</p> <ul style="list-style-type: none"> • Online: To submit a defense online, visit www.nyc.gov/oath. • Phone: To schedule a hearing by phone, call (212) 436-0817. • Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038. <p>To present a defense in person:</p> <ul style="list-style-type: none"> • You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons. • If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below). • Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you. • If you require assistance with English, free language assistance will be provided. <p>Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.</p>			
<p>Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.</p>			
<p>OATH HEARINGS CENTERS</p> <p>Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath</p> <p>Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038 Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201 Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435 Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455 Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301</p>			

The Tabak hearing transcript is annexed separately as Exhibit 5.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>MALKY TABAK 585 MARCY AVENUE, APT.#2E BROOKLYN, NY 11208</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30198-19L0</u></p> <p>Decision Date: <u>8/29/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq. Lorraine Peone, Esq. and Dr. Jennifer Rosen, M.D.</u></p> <p>Type of Hearing: <u>In Person</u></p>
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Summary Disposition: Sustained

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05. The summons' issuance date was April 21, 2019.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who</p>	Sustained	\$1,000.00

David Leung

			<p>live, work or reside in certain zip codes in Williamsburg, Brooklyn, which included zip code 11206 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which was issued on April 21, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order. In support of his argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>Moreover, Respondent argues that he cannot be liable for violating the Board's Resolution because service by publication of the Resolution pursuant to NYC Administrative Code 17-148 was not effectuated until April 24, 2019, which is after the date of issuance. (R1 is a copy of the City Record Online, which shows that the Resolution was published therein for 3 consecutive days from 4/22/19 to 4/24/19).</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity, efficacy and safety of the MMR vaccine and to the fundamental fairness of the summons and Petitioner's authority to mandate vaccination. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order</p>		
--	--	--	--	--	--

Dell...

				<p>was settled in recent litigation (P4 is a copy of a decision by Hon. Lawrence Kripel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments are beyond the scope of this hearing, and as such, I make no findings as to Respondent's evidence or arguments in these areas.</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>I credit the testimony of the issuing inspector and the allegations contained in the summons and find that they support a violation of the cited section of law. I find that respondent failed to provide a defense to the allegations. This line item is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

Dell...

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
see OATH's website nyc.gov/oath
or call 1-844-OATH-NYC

GN3c Decision Back Health 5-4-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Malky Tabak

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30198-19L0

NOTICE OF APPEAL

Respondent Malky Tabak (“Mrs. Tabak”) hereby appeals the decision on Summons Number 30198-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On September 30, 2019, Mrs. Tabak submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on October 9, 2019, and set the deadline to file this appeal for Tuesday, November 12, 2019. Mrs. Tabak submitted a second *Request for Extension of Time to File Appeal* on November 7, 2019. OATH approved the second request on November 12, 2019, and set the deadline to appeal for December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On April 23, 2019, Mrs. Tabak was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child C.R. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summon should have been dismissed and that the Hearing Officer deprived Mrs. Tabak of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On April 23, 2019 Mrs. Tabak was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On August 28, 2019, David Leung (the "**Hearing Officer**") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated August 29, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference.

STANDARD OF REVIEW

"When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has

the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on April 23, 2019, alleges a violation that occurred on April 21, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Tabak alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Tabak violated the Commissioner’s Order on April 21, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p 58.** The Commissioner’s Order expired because the New York City Health Code provides that an emergency action “shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration[.]” NY City Health Code

(NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.² The Resolution defines the nuisance as the measles outbreak.³

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

² "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

³ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁴

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁴ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁵

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was April 21, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE RESOLUTION WAS NOT LEGALLY ENFORCEABLE UNTIL APRIL 25, 2019, AFTER THE DATE OF OCCURRENCE, AND THEREFORE NO VIOLATION EXISTED AS ALLEGED

Even assuming the Summons alleged a violation of the Resolution (which it did not), it was an error of law for the Hearing Officer to sustain the Summons because the Resolution was not legally enforceable until April 25, 2019, and the date of occurrence listed on Mrs. Tabak's Summons was April 21, 2019.

The Commissioner's Order was created pursuant to "public health emergency" powers

⁵ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." Petitioner-Appellee's Hearing Exhibit 2.

found at NY City Health Code (24 RCNY) § 3.01 (d). This provision explicitly grants the Commissioner the legal authority to make her order effective immediately. On the other hand, the Resolution was published pursuant to New York City Admin. Code § 17-148, and this code section does not grant the Board the authority to make its order effective immediately.

Instead, where the Board passes a resolution, NYC Admin. Code § 17-148 (c) requires publication of the notice “for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order.” Notice via publication is not legally sufficient until the expiration of the third day of publication. *Id.*

The Board published the Resolution in the City Record April 22, 2019, through April 24, 2019. **Respondent-Appellant’s Hearing Exhibit 1.** Thus, notice of the Resolution was not legally sufficient until April 25, 2019 (i.e., the expiration of the third day of publication). Petitioner-Appellee, therefore, cannot issue a violation of the Resolution for an occurrence prior to April 25, 2019.

When asked to rebut this fact at the hearing, Petitioner-Appellee presented no legal argument, only stating that the Resolution was immediately effective. **Exhibit C, Hearing Transcript, pp 86-87.**

As discussed above, the Commissioner’s Order “was only effective until the next meeting of the Board.” NY City Health Code (24 RCNY) § 3.01 (d). Thus, the Commissioner’s Order expired on April 17, 2019. Consequently, from April 17, 2019, through April 24, 2019, neither the Commissioner’s Order nor the Resolution was in force or effect. Mrs. Tabak is alleged to have violated the Commissioner’s Order on April 21, 2019. Neither the Commissioner’s Order nor the Resolution was in effect on this date; therefore, it was an error of law for the Hearing Officer to sustain the Summons because no violation existed as alleged, and as such, the Tribunal must

dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. TABAK AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Tabak. Due process requires that Mrs. Tabak be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Tabak be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁶

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school,

Petitioner-Appellee's Hearing Exhibit 2. Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Tabak from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles." **Exhibit A, Summons.** This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Tabak must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Tabak is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Tabak of mounting a viable

preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. *See, argument at Section I, p 5.*

defense to the Summons. Furthermore, Mrs. Tabak was clearly not provided “an accurate statement of the matter to be adjudicated” as required by NYCC § 1046.

In sum, the Commissioner’s Order and the Board’s Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Tabak an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. TABAK OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Tabak of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Tabak proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Tabak’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“**Dr. Rosen**”), was available and could answer any questions regarding these

disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child's address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Tabak to determine if the child had been given MMR before the Summons was issued (**Hearing Transcript, p 117-118**).

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Tabak the ability to cross-examine the issuing officer and deprive Mrs. Tabak of a full and fair hearing, and the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. TABAK OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Tabak of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Tabak's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Tabak's counsel of the chance to reasonably cross-

examine Dr. Rosen and deprived Mrs. Tabak of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Tabak "*relied upon* the last paragraph of the Order, which states, '[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board'" to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Tabak did not *rely upon* this statement made in the Commissioner's Order. Instead, Mrs. Tabak's argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner's Order. In fact, counsel for Mrs. Tabak read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Tabak paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Tabak made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer's authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding

this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Tabak made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Tabak as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and

is not factually supported; hence, Mrs. Tabak was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 - *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 - CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 – British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 – NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* (“M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility”).

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VIII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁷ Mrs. Tabak reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

⁷ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

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DOHMH v. Malky Tabak
30198-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH vs J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30198-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 3) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of the Resolution is applied to the Summons, the Respondent will still be found in violation since

Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Resolution took effect on April 17, 2019 and continues the Commissioner's Order therefore the Summons should not be dismissed

The Board of Health in the final paragraph of the Resolution declares that the Resolution takes effect immediately on April 17, 2019. The Board of Health's inclusion of the effective date makes it clear that the Board of Health intended the Resolution to take effect on April 17, 2019 and not at the end of publication. The question of whether the Board of Health has the power in a public health emergency to make a Resolution effective prior to the completion of publication under New York City Administrative Code 17-148 is a question more in the jurisdiction of another tribunal. In fact, in *C.F. v. NYC Department of Health and Mental Hygiene*, 2019 NY Slip Op 31047 (April 18, 2019), Judge Lawrence S. Knipel reviewed the Commissioner's and Department's decision in issuing the Resolution and Commissioner's Order finding a rational basis for declaring the public health emergency and issuing the orders using the least restrictive legally available means.

Moreover, even if found that the Resolution was not in effect until completion of publication, as discussed above, the Resolution is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order. The Order was issued on April 9, 2019 and continued April 17, 2019 by the Board of Health. *See DOHMH vs J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order).

Accordingly, the decision should be affirmed.

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged ...; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be

violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted." The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges the hearing officer's decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer's findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer's decision is based on the credibility of the evidence presented, the Hearing Officer's decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation for a specified violation, as defined by paragraph (b) of subdivision 4 of this section, when dismissal is appropriate in the interest of justice, within the meaning of this subdivision”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent's appeal.

Accordingly, the decision should be affirmed.

VIII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (Appeal page 19, footnote 7), Respondent's Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
 Brooklyn, NY 11201

APPEALS DECISION

DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against- MALKY TABAK 585 MARCY AVENUE, APT.#2E BROOKLYN, NY 11206 (Respondent)	Violation/Summons No.: <u>30198-19L0</u> Decision Date: <u>5/5/2020</u> Hearing Officer: <u>Zeitler Richard</u> Respondent's Rep.: <u>Aaron Siri, Esq.</u> Petitioner's Rep.: <u>Thomas Merrill, Esq. Lorraine Peone, Esq. and Dr. Jennifer Rosen, M.D.</u> Type of Hearing: <u>Appeal</u>
--	---

Summary Disposition: AFFA

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30198-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 29, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30198-19L0	HC § 3.05	In Violation	Affirmed -- In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed on April 23, 2019, that on April 21, 2019, she reviewed the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), and observed that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's personal knowledge. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Appeal No. 30198-19L0

DOHMH v. J. Doe

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codes,⁴ and that the child was not vaccinated. Respondent argued that the Order had already expired on the date of the summons and that Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that she could not be charged with violating the Resolution because the summons was issued before the required three-day publication period was completed. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents offered by Respondent regarding the efficacy and safety of the vaccination in general were taken into the record.

Petitioner noted that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an Order, which would be effective until the next BOH meeting. Petitioner argued that despite minor differences in language, the Resolution issued at that meeting continued the requirement already in effect that people be vaccinated, that the Resolution was by its terms effective immediately, and that publication had bearing only on the question of service. Petitioner's submissions included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁶

In the decision, the hearing officer sustained the violation, finding that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order, and the Board by its Resolution, directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer noted that Respondent made a variety of Constitutional and scientific arguments and challenges to the validity, efficacy and safety of the MMR vaccine and to the fundamental fairness of the summons and Petitioner's authority to mandate vaccination.⁷ The hearing officer noted, as well, Petitioner's responses and the NYS Supreme Court decision denying injunctive relief from the Order. See footnote 5 below. The hearing officer found that the Constitutional and scientific arguments were beyond the scope of the hearing. He found that the BOH Resolution of April 17, 2019, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019, and he found that Respondent failed to provide a defense to the allegations.

⁴ The DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ See 2019 NY Slip Op 31047 (April 18, 2019).

⁷ "MMR" stands for Measles, Mumps, Rubella.

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On appeal, Respondent repeats the arguments made in the hearing.⁸ In addition, Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the New York City Charter (NYCC), found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution of April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, which is that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the stated intent of the Resolution was to be effective immediately, i.e., on April 17, 2019, and that the question of whether the BOH has the power in a public health emergency to make a Resolution effective prior to completion of publication under NYC Administrative Code (Code) § 17-148 "is more in the jurisdiction of another tribunal." Petitioner further argues that even if it is found that the Resolution was not in effect until completion of publication, the Resolution "is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order." Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency.

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

Appeal No. 30198-19L0

DOHMH v. J. Doe

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Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order requiring that any person living, working or residing in those ZIP codes who had not received the MMR vaccine be vaccinated within forty eight hours of the Order being signed, unless such person could demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement. The Order further ordered that the parent or guardian of any such child older than six months of age should cause such child to be vaccinated within that forty-eight hour period unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019; the Order remained in effect at least until the BOH met on April 17, 2019. As the summons in this case was dated after April 17, 2019, Respondent argues that it must be dismissed because by that date the Order had expired. That is not correct. The summons, which was issued on April 23, 2019, was based on an examination of Petitioner's records that took place on April 21, 2019; that examination provided uncontroverted evidence that the child was not vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to

Appeal No. 30198-19L0

DOHMH v. J. Doe

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comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child was subsequently vaccinated.

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, it was for Respondent to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.⁹ There is no evidence in this record to show that Respondent offered any proof of immunity or any documentation that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁰ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician had personal knowledge of the same vaccination records examined by the IO and was available to testify. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections raised are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

⁹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹⁰ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30212-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Bella Englander ID NUMBER: 50092096

ADDRESS: 252 Keap Street APT# 4, Brooklyn NY 11211 PHONE: _____

DATE AND TIME OF OCCURRENCE: May 1, 2019, 11:30 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 252 Keap Street APT# 4, Brooklyn NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 12, 2019 AT: 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan Staten Island Bronx Queens XX Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.E., who is at least six months old, lives at 252 Keap Street APT# 4, Brooklyn NY 11211, which is located in one of the affected zip codes listed in the Order. On May 1, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.E. has no record of measles immunization. Respondent has failed to vaccinate child Z.E. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling Signature Date 05/02/2019

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons. Received by:

Print Name Signature Title Date

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
 Petitioner,

Summons No.
30212-19L0

- against -

BEILA ENGLANDER,
 Respondent.

August 28, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORRAINE PEONE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department Of Health And Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

PETITIONER'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

RESPONDENT'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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1	04/09 Commissioner Order	8	9
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2	04/17 Board of Health Resolution	8	9
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3	MMR Guide	11	11
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<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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PROCEEDINGS

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1 H.O. DAVID LEUNG: We're on the record.
2 Today's date is August 28, 2019. It's 1:37 in the
3 afternoon. We're here today on the Health Department
4 issued Summons No. 30212-19L0. I'm going to ask the
5 Department of Health, is the name listed here -- for
6 privacy reasons, I don't want to say it -- is this a
7 parent or a child?

8 MR. THOMAS MERRILL: The name is the
9 parent. The initials are the child.

10 H.O. LEUNG: Okay. The parent is -- I'm
11 going to just use the initials for privacy reasons --
12 is B-E. Respondent's attorney is here. What is your
13 name, sir?

14 MR. AARON SIRI: Aaron Siri.

15 UNIDENTIFIED FEMALE 1: We're on 30212,
16 right?

17 H.O. LEUNG: Yes.

18 UNIDENTIFIED FEMALE 1: Okay.

19 H.O. LEUNG: Mr. Siri, you see the name of
20 your client here. Do you have any objection to me
21 just using the initial for privacy reasons?

22 MR. SIRI: No objection.

23 H.O. LEUNG: Okay. Mr. Siri, before we
24 begin the hearing, you have a right to an
25 interpreter. Do you need one? Because I have to say

PROCEEDINGS

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1 that for the record. The issuing officer is not
2 here. You have a right to request that the officer
3 who wrote the summons appear.

4 MR. SIRI: Same objection as last hearing,
5 Your Honor.

6 H.O. LEUNG: Okay. Let's just put it on
7 the record. You object to the officer being here?
8 Not being here?

9 MR. SIRI: Yes. To respond to the details
10 of the violation or description, as previously
11 argued.

12 H.O. LEUNG: Okay. And I'm going -- I, I
13 made a ruling previously on the other hearing that,
14 and I'm going to make the ruling on the record here,
15 which is that the basis for your application, I find
16 that the issuing officer is not needed to allow you
17 to have a full and impartial and fair hearing, in the
18 sense that any questions you have can be addressed by
19 the witnesses present here and the representatives
20 that are present. I'm going to ask the Department of
21 Health to put your name on the record.

22 MR. THOMAS MERRILL: Thomas, Thomas
23 Merrill, Department of Health.

24 H.O. LEUNG: Counsel?

25 MS. LORRAINE PEONE: Lorraine Peone,

PROCEEDINGS

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1 attorney for the Department of Health.

2 H.O. LEUNG: And can you spell your last
3 name for me?

4 MS. PEONE: P-E-O-N-E.

5 H.O. LEUNG: Thank you. And we have a
6 doctor here. What is your name?

7 DR. JENNIFER ROSEN: Jennifer Rosen.

8 H.O. LEUNG: R-O-S-E-N?

9 DR. ROSEN: Correct.

10 H.O. LEUNG: Doctor, do you swear or affirm
11 the testimony you give will be the truth?

12 DR. ROSEN: I do.

13 [WHEREUPON THE WITNESS, J E N N I F E R R
14 O S E N, WAS DULY SWORN.]

15 H.O. LEUNG: Thank you. Mr. Siri, you
16 understand you have the right to appeal my decision
17 and so does the Department of Health?

18 MR. SIRI: Yes.

19 H.O. LEUNG: You also understand that the
20 line item charging an allegation of New York City
21 Health Code 3.05 carries a penalty of \$1,000 if found
22 in violation?

23 MR. SIRI: Yes. I just want to confirm the
24 objections and limitation, the elimitations
25 [phonetic] from the last hearing carry forward. In

PROCEEDINGS

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1 terms of asking questions and testimony.

2 H.O. LEUNG: Sure. Whatever you put on the
3 record speaks for itself in terms of your objection,
4 and that record is made part of this. Before we put
5 that record here, I just want to establish, to begin
6 the hearing, the summons alleges that -- let me just
7 read it real quick.

8 MR. SIRI: Happy to stipulate to what it
9 says, but I'm --

10 H.O. LEUNG: Do you want to? You, you're
11 entitled to.

12 MR. SIRI: I'm happy to stipulate the
13 violation speaks for itself.

14 H.O. LEUNG: Okay. You can waive the
15 formal reading of the --

16 MR. SIRI: Yeah --

17 H.O. LEUNG: -- of the violation.

18 MR. SIRI: -- I waive it.

19 H.O. LEUNG: You waive it?

20 MR. SIRI: Yeah.

21 H.O. LEUNG: Okay. Right.

22 MR. SIRI: Is there, is there a reason not
23 to?

24 MR. MERRILL: No, again --

25 H.O. LEUNG: No.

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1 MR. MERRILL: -- most often there's not
2 lawyers coming in, so --

3 H.O. LEUNG: It allows a Respondent who's
4 not represented when I read it to them so they
5 understand the nature of charges. Very often, they
6 don't even know what's written on the summons.

7 MR. SIRI: Understood. I, I waive the
8 reading. Thank you.

9 H.O. LEUNG: Okay. Understand. I hear
10 real quick and apologize [unintelligible] [00:03:30].
11 Do you have an extra copy of the summons?

12 MS. PEONE: I don't have an extra copy.
13 [unintelligible] [00:03:35]

14 H.O. LEUNG: Alright, I'll just make a copy
15 of it. Okay, I'm going to turn to the Department of
16 Health and ask what, if any, documents or testimony
17 evidence you have.

18 MR. MERRILL: Yeah, I'm going to -- just
19 like in the last case, I -- they're stapled together,
20 but it's going to be Respondent's 1 and 2, which is
21 the April 9th Commissioner Order and then the April
22 17th Board of Health Resolution, which ordered the
23 people in the -- residing [unintelligible]
24 [00:04:05] living in Williamsburg [unintelligible]
25 [00:04:08].

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1 MR. SIRI: No objection.

2 H.O. LEUNG: P-1 and P-2 are admitted
3 without objection.

4 **[Petitioner's Exhibits 1 and 2 admitted**
5 **into evidence.]**

6 H.O. LEUNG: Anything else? Do you --
7 other than relying on the summons?

8 MR. MERRILL: Rely on the summons, Your
9 Honor.

10 H.O. LEUNG: Okay. They're relying on the
11 sworn allegations of the summons. They're also
12 relying on P-1 and P-2. I'm going to turn to you,
13 Mr. Siri. Do you have any testimony or defense you
14 want to offer?

15 MR. SIRI: Just two things. First is, can
16 we stipulate to all of the, all of the defenses
17 raised in Summons No. 30198-19L0?

18 H.O. LEUNG: The record should reflect that
19 that Summons No. 30198-19L0 was the first in a series
20 of 19 hearings that counsel Mr. Siri is representing
21 on the Health Department allegations regarding MMR
22 vaccination. The first hearing, that summons number
23 that we just read into the record, lasted
24 approximately three hours, a little bit under three
25 hours, and in that hearing Mr. Siri made an extensive

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1 record in terms of introducing approximately over 45
2 documents consisting of over six, 700 pages, and he
3 made an extensive Constitutional and substantive
4 argument in defense of his client. We agreed in that
5 hearing that because the defenses to the subsequent
6 18 summonses will be similar in the sense that he
7 will be raising similar Constitutional defenses, that
8 the arguments in that first summons, 30198-19L0, will
9 be referred to in this record and incorporated as
10 part of this record to save time. So, Mr. Siri has
11 just posed the question to the Department of Health's
12 counsel, Mr. Merrill, as to whether or not he agrees
13 that the defenses and arguments raised in that first
14 hearing are similarly raised as the record reflects
15 in this hearing.

16 MR. MERRILL: For the sake of efficiency,
17 Your Honor, we're willing to agree that the arguments
18 are raised and the arguments made by both sides are
19 made in this record as well. I would point out
20 there's one different in one of the arguments here,
21 that this summons was served on May 1st. That's one
22 difference on the particularly notice argument. I
23 also would want to supplement where one of our
24 exhibits that --

25 H.O. LEUNG: Sure, whatever you need.

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1 MR. MERRILL: Okay. And this again reads -
2 - I would make a part of all of them [unintelligible]
3 [00:06:38] it's, it's the list of contraindications
4 for the MMR vaccine. I [unintelligible] [00:06:44] I
5 only have one copy, if I could [unintelligible]
6 [00:06:46]

7 H.O. LEUNG: Okay, I'm going to mark this
8 as Petitioner's 3. It's a two-page document. It's a
9 guide to contradictions, apparently.

10 MS. PEONE: Could I get a copy for --

11 H.O. LEUNG: Okay. Here, Counsel, there's
12 a copy for you. Mr. Siri, no objection?

13 MR. SIRI: I have no objection to that --

14 H.O. LEUNG: Okay, P-2 --

15 MR. SIRI: -- [unintelligible] [00:07:09] -

16 -

17 H.O. LEUNG: I'm sorry, this should be P-3.

18 MR. SIRI: -- violation.

19 H.O. LEUNG: I apologize. P-3.

20 **[Petitioner's Exhibit 3 admitted into**
21 **evidence.]**

22 MR. MERRILL: And if we're going to overlap
23 in different -- just you might want to make it --
24 because there was a P-3 in the earlier case.

25 H.O. LEUNG: Got you. Okay. The record

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1 should reflect that to the extent that P-1, P-2 and
2 P-3 are admitted here, it does not replace -- the
3 documents that are introduced in the hearing 30198-
4 19L0 pertain to the admission of Respondent's
5 documents only and not Petitioner's documents. Do
6 you --

7 MR. MERRILL: I, I would want my documents
8 that came in too, but I just --

9 H.O. LEUNG: No, no. On the original
10 hearing, all your documents are coming in.

11 MR. MERRILL: Yeah, okay.

12 H.O. LEUNG: And those, they stand for
13 themselves on that hearing. P-1 through P-3 that are
14 now, that I've marked for this hearing, you don't
15 want to be brought into that hearing, right?

16 MR. MERRILL: I do want 3.

17 H.O. LEUNG: You want 3? Okay.

18 MR. MERRILL: Yeah, the, the other one --
19 if we could save time, I'm going to be putting the
20 Order into all the cases as well, so actually if
21 they're in, they don't need to be in --

22 H.O. LEUNG: Got you.

23 MR. MERRILL: -- because the Order, you
24 know --

25 H.O. LEUNG: It's the same Order --

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1 MR. MERRILL: Yes, exactly.

2 H.O. LEUNG: -- as everything? Okay.

3 MR. MERRILL: Yeah.

4 H.O. LEUNG: Do you understand? P-1 and P-

5 2 are the exact same as P-1 and P-2 in the original.

6 MR. SIRI: Yeah, I understand that these

7 are same. Right.

8 MR. MERRILL: Correct.

9 MR. SIRI: So, and also the evidence that I

10 -- and, and just we're incorporating the argument and

11 also the evidence from the first case, 30198-19L0,

12 all comes into this case, too.

13 H.O. LEUNG: Correct. All your --

14 MR. SIRI: Okay.

15 H.O. LEUNG: -- documents from --

16 MR. SIRI: Right.

17 H.O. LEUNG: -- R-1 to R, I believe 45, are

18 in.

19 MR. SIRI: So to just respond to the, you

20 know, the fact that the date is May 1st. I don't

21 believe that that changes the, the, both of the

22 arguments that were made regarding that the violation

23 only relates to the Order, which expired on April

24 17th, and also that the publication, oh, the publica-

25 , May 1st was after the three days of publication, so

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1 that argument wouldn't apply here. Thank you.

2 H.O. LEUNG: Okay.

3 MR. SIRI: But other than that, I'll make
4 one last point on the record that the client has 10
5 children, I'm advised, and that they're all up to
6 date on vaccines. This is the only child that's not
7 been vaccinated. The mother has concerns and has
8 indicated she intends to vaccinate. She is holding
9 off for now until the child is older so she can see
10 what underlying issues the child has.

11 H.O. LEUNG: Okay. What's the, what's the
12 concern? Because that could be a basis for one of
13 the defenses, which is medical exemption. What is
14 the basis for the --

15 MR. SIRI: That the child is not
16 immunologically capable of handling this vaccine
17 without getting in, without having a serious
18 reaction.

19 H.O. LEUNG: Okay. And the basis for her
20 knowing that is she is informed by someone? Or is
21 that just her own personal opinion?

22 MR. SIRI: I mean, who knows a child better
23 than their own mother?

24 H.O. LEUNG: Did she consult --

25 MR. SIRI: In terms of --

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1 H.O. LEUNG: -- with a physician?

2 MR. SIRI: I believe she has a doctor.

3 H.O. LEUNG: Okay.

4 MR. SIRI: I'm assuming she spoke with her

5 doctor. No reason to assume otherwise.

6 H.O. LEUNG: Okay, Mr. Siri has offered

7 testimony evidence that the child, that the nine

8 other children are properly vaccinated and that the

9 mother of this child intends to vaccinate and is

10 holding off because the mother was informed,

11 according to Mr. Siri by a physician, that --

12 MR. SIRI: [unintelligible] [00:10:18]

13 H.O. LEUNG: Based on information and

14 belief.

15 MR. SIRI: Yeah.

16 H.O. LEUNG: That the child is not -- I

17 don't know what the term is -- at this time a

18 doctor's recommending that they hold off.

19 MR. MERRILL: There's been nothing

20 submitted, Your Honor, and that would be our

21 position. She -- I, I accept the representation

22 about the other kids. I don't know if it's true or

23 not. I haven't looked into the [unintelligible]

24 [00:10:40] on that. But the fact of the matter is,

25 this kid was over a year at the time, should've been

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1 vaccinated. There is no -- I'm going to --

2 H.O. LEUNG: I understand your argument,
3 and I'm going to give Mr. Siri one opportunity --

4 MR. MERRILL: Okay.

5 H.O. LEUNG: -- at this point. Do you have
6 any documents to, to prove the assertion that this
7 child is exempt, or would you like an adjournment to
8 have the mother produce a document? The letter has
9 to obviously be relevant in terms of the time of
10 defense. If you want, I'm giving you that
11 opportunity. Or do you rely on your testimony?
12 Well, actually, let me just --

13 MR. SIRI: I think we'll rest on the
14 current record.

15 H.O. LEUNG: Okay. I apologize.

16 MR. SIRI: I know. I believe it's this --
17 I -- like I've said in the last time, I believe it's
18 the Department's burden with regards to showing that
19 it's safe and effective to give it to the child and
20 this is the mother's conclusion based on my
21 understanding according to her knowledge of the
22 child, including the child's -- she raised, she gave
23 birth to child, she raised the child, she knows the
24 child, she knows the child's medical history and she
25 knows their child's doctors and she's obviously

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1 somebody who's vaccinated apparently nine of her
2 other kids. The MMR, she wants to just hold off for
3 now. There are -- she has medical concerns, intends
4 to give the vaccine in the future. I'll just rest on
5 that.

6 H.O. LEUNG: Okay. Anything further from
7 either side?

8 MR. MERRILL: No.

9 H.O. LEUNG: Hearing nothing further, this
10 hearing is concluded. You'll receive a written
11 decision in 30 days. I'm taking the case under
12 advisement. Thank you.

13 [END OF HEARING]

14

15

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health and Mental Hygiene v. Beila Englander on August 28, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC.

256 West 38th Street - 10th Floor

New York, NY 10018


OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
 Hearings Division

 9 Bond Street, 7th Floor
 Brooklyn, NY 11201

SUPERSEDING DECISION

DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against- BEILA ENGLANDER 252 KEAP STREET, APT.#4 BROOKLYN, NY 11211 (Respondent)	Violation/Summons No.: <u>30212-19L0</u> Decision Date: <u>8/29/2019</u> Hearing Officer: <u>Leung David</u> Respondent's Rep.: <u>Aaron Siri, Esq.</u> Petitioner's Rep.: <u>Thomas Merril, Esq., Lorraine Peone, Esq. and Dr. Jennifer Rosen, MD</u> Type of Hearing: <u>In Person</u>
--	--

 Summary Disposition: **Sustained**

THIS DECISION AND ORDER SUPERSEDES ALL PRIOR DECISIONS AND ORDERS.

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on May 1, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who</p>	Sustained	\$1,000.00

				<p>live, work or reside in certain zip codes in Williamsburg, Brooklyn, which included zip code 11211 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of May 1, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order. In support of his argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments are beyond the scope of the hearing, and as such, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued</p>		
--	--	--	--	--	--	--

D. L. Knipel

				<p>the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>On the merits of the case, Respondent stated that the child's mother didn't vaccinate the child because she thought the child was not physically able to accept the vaccination.</p> <p>I credit the testimony of the issuing inspector and the allegations contained in the summons and find that they support a violation of the cited section of law. I find that respondent failed to provide a defense to the allegations. This line item is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

D. J. [Signature]

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
see OATH's website nyc.gov/oath
or call 1-844-OATH-NYC

GADC Decision Back Health 5-9-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Beila Englander

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30212-19L0

NOTICE OF APPEAL

Respondent Beila Englander (“Mrs. Englander”) hereby appeals the decision on Summons Number 30212-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On September 30, 2019, Mrs. Englander submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on October 9, 2019, and set the deadline to file this appeal for Tuesday, November 12, 2019. Mrs. Englander submitted a second *Request for Extension of Time to File Appeal* on November 7, 2019. OATH approved the second request on November 12, 2019, and set the deadline to appeal for December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On May 2, 2019, Mrs. Englander was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child Z.E. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mrs. Englander of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On May 2, 2019 Mrs. Englander was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On August 28, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated August 29, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19LO.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19LO into the record for Mrs. Englander's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on May 2, 2019, alleges a violation that occurred on May 1, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Englander alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Englander violated the Commissioner’s Order on May 1, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p 58.** The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was May 1, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. ENGLANDER AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Englander. Due process requires that Mrs. Englander be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached)

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Englander be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Englander from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. See, argument at Section I, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Englander must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Englander is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Englander of mounting a viable defense to the Summons. Furthermore, Mrs. Englander was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Englander an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. ENGLANDER OF A FULL AND FAIR HEARING

BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Englander of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

"A respondent may request the [issuing officer's] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful." *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Englander proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Englander's application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen ("Dr. Rosen"), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child's address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Englander to determine if the child had been given MMR before the Summons

was issued (Hearing Transcript, p 117-118).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Englander the ability to cross-examine the issuing officer and deprive Mrs. Englander of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. ENGLANDER OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Englander of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Englander's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Englander's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Englander of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Englander's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Englander “*relied upon* the last paragraph of the Order, which states, “[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Englander did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mrs. Englander’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mrs. Englander read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Englander paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Englander made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Englander made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support

this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Englander as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mrs. Englander was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines. Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological, Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpura" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal. Additionally, Mrs. Englander has ten children and all but the child receiving the summons are up-to-date with vaccinations. Mrs. Englander delayed MMR vaccination with this child because she had concerns about the child's ability to tolerate the vaccine. **Exhibit C, Part C, Hearing Transcript pp 9-11.**

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Englander reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

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DOHMH v. Beila Englander
30212-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30212-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Resolution took effect on April 17, 2019 and continues the Commissioner's Order therefore the Summons should not be dismissed

The Board of Health in the final paragraph of the Resolution declares that the Resolution takes effect immediately on April 17, 2019. The Board of Health's inclusion of the effective date makes it clear that the Board of Health intended the Resolution to take effect on April 17, 2019 and not at the end of publication. The question of whether the Board of Health has the power in a public health emergency to make a Resolution effective prior to the completion of publication under New York City Administrative Code 17-148 is a question more in the jurisdiction of another tribunal. In fact, in *C.F. v. NYC Department of Health and Mental Hygiene*, 2019 NY Slip Op 31047 (April 18, 2019), Judge Lawrence S. Knipel reviewed the Commissioner's and Department's decision in issuing the Resolution and Commissioner's Order finding a rational basis for declaring the public health emergency and issuing the orders using the least restrictive legally available means.

Moreover, even if found that the Resolution was not in effect until completion of publication, as discussed above, the Resolution is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order. The Order was issued on April 9, 2019 and continued April 17, 2019 by the Board of Health. *See DOHMH vs J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order).

Accordingly, the decision should be affirmed.

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted." The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours

adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The summons should not be dismissed because Respondent alleges the hearing officer's decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that "the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law."

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer's findings, however, that is not grounds to reverse the decision. It has been held that "[w]here evidence conflicts and a Hearing Officer's decision is based on the credibility of the evidence presented, the Hearing Officer's decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance." *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) ("...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*") (emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent's appeal.

Accordingly, the decision should be affirmed.

VIII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent's Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>BEILA ENGLANDER 252 KEAP STREET, APT.#4 BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30212-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merril, Esq., Lorraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
--	--

Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30212-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 29, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30212-19L0	HC § 3.05	In Violation	Affirmed -- In Violation	\$1,000

BACKGROUND

In the summons, on May 2, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 1, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons states that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties stipulated that all the arguments made and evidence submitted in the previous hearing for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Petitioner

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Appeal No. 30212-19L0

DOHMH v. J. Doe

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submitted an additional document consisting of a list of contraindications for the MMR vaccine.⁴ Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁵ and that the child was not vaccinated. As in the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁶ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued.⁷ Respondent argued again that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also referenced. In this hearing, Respondent added that the mother of this child has 10 other children, all up-to-date on vaccines; that she is waiting to provide the vaccination when the child is older because she “believes the child is not immunologically capable of handling this vaccine without having serious reactions.”

Petitioner’s arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH’s power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued this Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself was an order under HC § 3.05 for which notice was provided in the narrative of the summon. Petitioner further argued that the Resolution was by its terms effective immediately, and that publication had bearing only on the question of service. Petitioner’s previous submissions included “Frequently Asked Questions” regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ As to Respondent’s assertion that the child was not capable of handling immunization at this time, Petitioner stated that nothing to that effect was submitted to the Petitioner and noted that the child was over a year old.

In the decision, the hearing officer found that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order and the Board by its Resolution directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer rejected Respondent’s argument that the Order had expired when the summons was written,

⁴ “MMR” stands for Measles, Mumps, Rubella.

⁵ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁶ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁷ As this summons was written after the Resolution’s three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

Appeal No. 30212-19L0

DOHMH v. J. Doe

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finding that the BOH Resolution of April 17, 2019, had continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Order. The hearing officer found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. He credited the IO and the allegations contained in the summons and found that they support a violation of the cited section of the law. The hearing officer noted Respondent's assertion that the child's mother did not vaccinate the child because she thought the child was not physically able to accept the vaccination. However, he found that Respondent had failed to provide a defense to the allegations and he sustained the violation.

On appeal, Respondent repeats the arguments raised in the prior hearing relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles, and the specific argument in this case that service of the summons was not proper.⁹ In addition, Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the NYCC, found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution dated April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

⁹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

Appeal No. 30212-19L0

DOHMH v. J. Doe

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HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order requiring that any person living, working or residing in those ZIP codes who had not received the MMR vaccine be vaccinated within forty-eight hours of the Order being signed, unless such person could demonstrate immunity to the disease or document to the satisfaction of the Department that he or she should be medically exempt from this requirement, and ordered that a parent or guardian of a child older than six months have the child vaccinated unless the parent or

Appeal No. 30212-19L0

DOHMH v. J. Doe

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guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019. The Order remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was served after the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 1, 2019. That examination provided uncontroverted evidence that the child had never been vaccinated, and therefore was not vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish¹⁰. There is no evidence in this record to show that Respondent offered any proof of immunity or documentation that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable.¹¹ Respondent did not offer proof to contest any of the essential facts establishing the violation so as to shift the burden back to Petitioner, *see* 48 RCNY § 6-12(b) (the summons, if affirmed, "will be admitted as prima facie evidence of the facts stated therein), and, in any case, the DOHMH physician had personal knowledge of the same vaccination records examined by the IO and was available to testify.

As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹¹ *See Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30216-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Basia Hauer ID NUMBER: 50092097

ADDRESS: 201 HOOPER ST, Brooklyn NY 11211 PHONE: _____

DATE AND TIME OF OCCURRENCE: May 1, 2019, 11:35 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 201 HOOPER ST, Brooklyn NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 12, 2019 AT: 10:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan
66 John Street
10th & 11th Floor
New York, NY 10038
- Staten Island
350 St. Marks Place
Main Floor
Staten Island, NY 10301
- Bronx
3030 Third Avenue
Room 250
Bronx, NY 10455
- Queens
31-00 47th Avenue
3rd & 4th Floor
Long Island City, NY 11435
- Brooklyn
9 Bond Street
6th & 7th Floor
Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019 the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.K., who is at least six months old, lives at 201 HOOPER ST, Brooklyn NY 11211, which is located in one of the affected zip codes listed in the Order. On May 1, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.K. has no record of measles immunization. Respondent has failed to vaccinate child Z.K. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see either side of this notice.

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling 05/02/2019

Print Name Signature ID Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by: _____

Print Name Signature Title Date:

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
 Petitioner,

Summons No.
30216-19L0

- against -

BAILA HAUER,
 Respondent.

August 28, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORRAINE PEONNE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department of Health And Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

PETITIONER'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

RESPONDENT'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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47.	Baila Klein Affidavit	11	12
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48.	Baila Klein Declaration	11	12
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PROCEEDINGS

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1 H.O. DAVID LEUNG: Okay, we're on the
2 record. Today's date is August 28, 2019. It's 2:00
3 in the afternoon. We're here today on Health
4 Department summons 30216-19L0 issued to initial BH.
5 This is a alleged violation of New York City Health
6 Code 3.05 regarding a MMR vaccination. We have two
7 attorneys for Department of Health.

8 MR. THOMAS MERRILL: Thomas Merrill.

9 MS. LORRAINE PEONNE: Lorraine Peonne.

10 H.O. LEUNG: And we have a physician from
11 the Department of Health.

12 DR. ROSEN: Jennifer Rosen [unintelligible]
13 [00:31].

14 H.O. LEUNG: Dr. Rosen, do you swear to
15 tell the truth?

16 DR. ROSEN: Yes.

17 [WHEREUPON THE WITNESS, J E N N I F E R R
18 O S E N, WAS DULY SWORN.]

19 H.O. LEUNG: Thank you. And we've got an
20 attorney from respondent.

21 MR. SIRI: Aaron Siri.

22 H.O. LEUNG: Mr. Siri, do you waive
23 interpretation and the need to have the issuing
24 officer appear?

25 MR. SIRI: Yes. I waive interpretation.

PROCEEDINGS

5

1 I waive a reading, but I don't waive the issuing
2 officer appearing. I ask that the arguments made on
3 30198-19L0 regarding having the officer appear be
4 incorporated by reference into this hearing.

5 MR. MERRILL: No objection.

6 H.O. LEUNG: The entire record of 30198-
7 19L0, all the documents admitted into the evidence
8 onto that hearing and the recording are incorporated
9 into this hearing. That hearing consisted of nearly
10 a three-hour hearing. The substance of the
11 allegations and the substance of the defense are the
12 same and both sides have agreed to incorporate the
13 recording of that hearing into the hearing at
14 present. Mr. Siri, you understand that both sides
15 have the right to appeal and that the line item
16 alleges a violation that car-, of New York City
17 Health Code 3.05 that carries a penalty of \$1,000 if
18 found in violation.

19 MR. SIRI: I do.

20 H.O. LEUNG: Okay. I'm going to turn to
21 the Department of Health and ask do you rely on the
22 documents that you admitted in the previous hearing
23 record which is P1, P2 and P3, P1 being the order of
24 the commissioner, P2 being the resolution of the
25 board, and P3 being a guide to contradictions?

PROCEEDINGS

6

1 MR. MERRILL: Yes, as well as the documents
2 -- we introduced some additional documents at the
3 first hearing.

4 H.O. LEUNG: Right, right, and all the
5 documents in the hearing.

6 MR. MERRILL: Yes.

7 H.O. LEUNG: Okay. And do you rely on the
8 sworn allegations of the issuing officer here?

9 MR. MERRILL: Yes.

10 H.O. LEUNG: Okay.

11 MR. SIRI: Okay.

12 H.O. LEUNG: Mr. Siri.

13 MR. SIRI: Yeah, so, and I agree to
14 incorporate all that by reference, the -- so we've
15 incorporated the first argument that the order
16 expired on the April 17th and that this summons was
17 issued after that date, also rely on the argument
18 that [unintelligible] [02:34]. Okay. So second
19 argument is going to be one of defective service. My
20 client's father who lives at a different apartment in
21 the building, lives on the first floor, was given the
22 summons. The father informed the officer that that's
23 not where the respondent lives, and the officer
24 submi-, said I will give it to her. And this is an
25 affidavit attesting to that.

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1 H.O. LEUNG: Can I see the affidavit of
2 service?

3 MR. MERRILL: It was mailed as well, Your
4 Honor.

5 H.O. LEUNG: Say again?

6 MR. MERRILL: It was mailed as well. It
7 was served on --

8 MR. SIRI: Yeah, but substitute
9 [unintelligible] [03:30] somebody else in the same
10 apartment and then mailing [unintelligible] [03:33].
11 Do you want to agree to withdraw this one by any
12 chance? A different apartment.

13 MR. MERRILL: No, because I have services
14 under 301.

15 MS. PEONNE: 301, yeah.

16 MR. SIRI: Yeah, alternative service. If
17 it was somebody else in the same apartment and then
18 mailed, I agree.

19 MR. MERRILL: No, no, but I'm talking about
20 --

21 MS. PEONNE: Service [unintelligible]
22 [03:55].

23 MR. MERRILL: Yeah, in terms of
24 [unintelligible] [03:58].

25 H.O. LEUNG: Let me just -- on the, on the,

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1 on the face of this, and we don't have the person
2 serving here, but on the face of this affidavit it
3 says that I -- I'm going read its substance. I,
4 Mr. Alvarado (phonetic), deputy sheriff from New York
5 City, authorize, certify that on May 2nd at
6 approximately 9:30 at 201 Cooper Street, Brooklyn,
7 New York -- it doesn't say an apartment number -- in
8 the borough of Brooklyn I served the annexed summons
9 on Baila Hauer in the following manner: personal
10 service by delivering to and leaving with Aaron
11 Hauer, a person of suitable age and discretion, who
12 stated he is the father to the defendant/respondent a
13 true copy [unintelligible] [04:41] address is the
14 home of the defendant/respondent. So on its face
15 the, the server is saying that he served the father
16 at respondent's home.

17 MR. SIRI: But it wasn't his home.

18 H.O. LEUNG: I understand. That's her
19 testimony. So I'm just saying --

20 MR. SIRI: Yeah.

21 H.O. LEUNG: There's a, there's a conflict
22 of fact here. So you're, you're, they're relying on
23 the affidavit of service. You're relying that --

24 MR. SIRI: Declaration I just gave you
25 under penalty of perjury.

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1 H.O. LEUNG: Right. So we have two, two
2 over here, right?

3 MR. SIRI: Yeah.

4 H.O. LEUNG: Because they're both under
5 penalty of perjury. So there's a -- do we agree
6 there's a conflict here? I mean, there's a conflict
7 in the sense that the address was correct. You're
8 saying that it was in the wrong apartment in the
9 building. Is that correct?

10 MR. SIRI: Yeah, he gave it to -- right, at
11 the father's apartment, not the respondent's
12 apartment which is a different floor.

13 H.O. LEUNG: And the respondent lives on
14 what floor?

15 MR. SIRI: Second.

16 H.O. LEUNG: Second floor. Correct. I'm
17 going to make a determination as to whether service
18 is proper and that's going to be part of my decision.

19 MR. SIRI: Okay.

20 H.O. LEUNG: Okay.

21 MR. SIRI: I've got a third argument for
22 this one.

23 H.O. LEUNG: Yeah.

24 MR. SIRI: Third argument is that the child
25 was under one year of age, and again the pro-, same

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1 argument as last time. The product is not licensed
2 for children under one year of age. It forms a, you
3 know, a defective form of immunity.

4 H.O. LEUNG: Okay.

5 MR. SIRI: Later.

6 H.O. LEUNG: I'm going to give DOH an
7 opportunity to respond because the doctor has
8 testimony at a previous hearing in response to the
9 one-year age appropriateness, and that's not part of
10 the initial record. So even though --

11 MR. SIRI: Yeah.

12 H.O. LEUNG: - the first is incorporated.

13 MR. SIRI: Understood.

14 H.O. LEUNG: So, Doctor --

15 MR. SIRI: Here you go.

16 H.O. LEUNG: He's raised the issue that
17 this is inappropriate for a child under one year, one
18 year old.

19 DR. ROSEN: The Advisory Committee on
20 Immunization Practices which sets the national
21 recommended schedule for immunizations recommends
22 that a dose of MMR vaccine be considered in an
23 outbreak setting to children ages six to 11.
24 Further, the Advisory Committee on Immunization
25 Practices routinely recommends the MMR vaccine be

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1 given to infants age six to 11 months prior to
2 international travel.

3 MR. SIRI: Okay. Just one question. Was,
4 has the MMR vaccine been licensed for children by the
5 FDA under one year of age?

6 DR. ROSEN: No, but that --

7 MR. SIRI: Okay.

8 DR. ROSEN: The Advisory Committee on
9 Immunization Practices is, sets the national
10 standards, and so there are instances where despite
11 licensure the committee makes different
12 recommendations.

13 H.O. LEUNG: I've marked as Respondent's 47
14 the affidavit from Baila Klein (phonetic) indicating
15 in substance that the, indicating that -- this is the
16 affidavit that her child is less than a year old. An
17 then R48 I'm going to mark as the declaration of
18 Baila Klein, the respondent, saying that she was
19 improperly served because her father was served on
20 the first floor and she lives on the second floor.
21 Any objection to 47 and 48 being admitted into
22 evidence?

23 MR. MERRILL: No.

24 H.O. LEUNG: They're admitted into
25 evidence.

PROCEEDINGS

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[Respondent's Exhibits 47 and 48 admitted into evidence.]

H.O. LEUNG: Is there anything else from either side?

MR. SIRI: No.

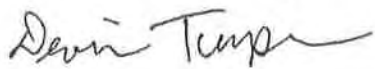
H.O. LEUNG: Hearing nothing, nothing hearing is concluded. I have enough to make a decision. I take the case under advisement. I'll issue a written decision within 30 days. Thank you.

[END OF HEARING]

CERTIFICATE OF ACCURACY

I, Devin Turpin, certify that the foregoing transcript of Department of Health and Mental Hygiene v. Baila Hauer on August 28, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By



Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE.</p> <p>-against-</p> <p>BAILA HAUER 201 HOOPER STREET BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30216-19L0</u></p> <p>Decision Date: <u>8/30/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Sin, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Lorraine Peonne, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
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Summary Disposition: Sustained

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on May 1, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes in Williamsburg, Brooklyn, which</p>	Sustained	\$1,000.00

Dell'Arc

				<p>included zip code 11211 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of May 1, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order. In support of his argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments are beyond the scope of the hearing, and as such, I make no findings as to the validity of</p>		
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D. J. [Signature]

				<p>Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent stated that service of the summons was improper because it was served upon Respondent's father, who lives on the first floor, while Respondent lives on the second floor. (See R's 48) On this record, I find that respondent's father is a person of suitable age and discretion as provided in OATH Rule 6-08(b)(1)(i)(H). Also, I find that Petitioner's mailing of the summons to respondent satisfied the service requirement of OATH Rules 6-08(b)(1)(ii).</p> <p>Respondent also argued that the MMR vaccine is not safe for a child under the age of 12 months. Dr. Rosen testified that in emergency/outbreak situations, an MMR vaccine is appropriate for a child older than six months. I credit Dr. Rosen's testimony as it pertains to this argument.</p> <p>I credit the testimony of the issuing inspector and the allegations contained in the summons and find that they support a violation of the cited section of law. I find that respondent failed to provide a defense to the allegations. This line item is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

Dell...

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You MUST use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal MUST be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you MUST pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you MUST use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
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or call 1-844-OATH-NYC

Cr-10 Decision Back Health 5-6-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Baila Hauer

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30216-19L0

NOTICE OF APPEAL

Respondent Baila Hauer (“Mrs. Hauer”) hereby appeals the decision on Summons Number 30216-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On September 30, 2019, Mrs. Hauer submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on October 9, 2019, and set the deadline to file this appeal for Tuesday, November 12, 2019. Mrs. Hauer submitted a second *Request for Extension of Time to File Appeal* on November 7, 2019. OATH approved the second request on November 12, 2019, and set the deadline to appeal for December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On May 2, 2019, Mrs. Hauer was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child Z.K. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summon should have been dismissed and that the Hearing Officer deprived Mrs. Hauer of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On May 2, 2019 Mrs. Hauer was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On August 28, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated August 30, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Hauer's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER'S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on May 2, 2019, alleges a violation that occurred on May 1, 2019, which is after the Commissioner's Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Hauer alleges a violation of the Commissioner's Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner's Order. The Commissioner's Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Hauer violated the Commissioner's Order on May 1, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner's Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously; occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was May 1, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE MRS. HAUER WAS NOT PROVIDED PROPER SERVICE OF THE SUMMONS

Another independent basis for dismissing the Summons exists because Mrs. Hauer was not provided proper service of the Summons. Mrs. Hauer was served The Summons was not properly personally served on Mrs. Hauer but rather on the tenant who lives on the first floor of Mrs. Hauer's building. **Respondent-Appellant's Hearing Exhibit 48, Declaration of Baila Klein, Improper Service.** Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Mrs. Hauer was not provided proper legal service, and the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

TO PROVIDE REASONABLE NOTICE TO MRS. HAUER AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Hauer. Due process requires that Mrs. Hauer be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Hauer be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently: the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." *Petitioner-Appellee's Hearing Exhibit 2*. (emphasis added.) The distinction between the words "live" and "reside" are legally significant. *See*, argument at Section I, p 5.

Petitioner-Appellee's Hearing Exhibit 2. Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Hauer from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles." **Exhibit A, Summons.** This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Hauer must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Hauer is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Hauer of mounting a viable defense to the Summons. Furthermore, Mrs. Hauer was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Hauer an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. HAUER OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Hauer of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

"A respondent may request the [issuing officer's] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful." *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Hauer proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Hauer's application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen ("Dr. Rosen"), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to

present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child's address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Hauer to determine if the child had been given MMR before the Summons was issued (**Hearing Transcript, p 117-118**).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Hauer the ability to cross-examine the issuing officer and deprive Mrs. Hauer of a full and fair hearing, and the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. HAUER OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Hauer of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Hauer's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240**. In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153**. Therefore, the Hearing Officer

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Hauer's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242**.

committed an error of law by preventing Mrs. Hauer's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Hauer of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Hauer "*relied upon* the last paragraph of the Order, which states, '[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board'" to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Hauer did not *rely upon* this statement made in the Commissioner's Order. Instead, Mrs. Hauer's argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner's Order. In fact, counsel for Mrs. Hauer read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Hauer paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Hauer made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer's authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p**

151 p 172; p183. Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Hauer made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Hauer as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and

is not factually supported; hence, Mrs. Hauer was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE IT WAS ARBITRARY AND CAPRICIOUS FOR THE HEARING OFFICER TO SUSTAIN A SUMMONS MANDATING A VACCINATION FOR A CHILD UNDER TWELVE MONTHS OLD WHERE THE FOOD AND DRUG ADMINISTRATION HAS NOT LICENSED THAT VACCINATION FOR CHILDREN UNDER TWELVE MONTHS OLD

The Tribunal should dismiss the Summons because it was arbitrary and capricious for the Hearing Officer to sustain the Summons mandating the MMR vaccine for a child less than twelve months old. Mrs. Hauer's child was less than twelve months old at the time of the alleged violation. **Respondent-Appellant's Hearing Exhibit 47, Declaration of Baila Klein, Child's Date of Birth.** The Food and Drug Administration ("FDA") has not licensed MMR for children less than twelve months old. Mrs. Hauer presented undisputed evidence at the hearing that the MMR vaccine is not licensed for this age group and that the "safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established." **Respondent-Appellant's Hearing Exhibit 30: Exhibit C, Part C, Transcript of Hearing, p 7.** Therefore, the Summons and the Hearing Officer's order are both saying that Mrs. Hauer's child must receive a vaccination even though the FDA has not determined that it is safe and effective for the child. This is patently arbitrary and capricious because there is no reasonable basis for the Hearing Officer to uphold a violation for failure to vaccinate a child with MMR where the vaccine is not licensed for use in the child.

VIII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

IX. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Hauer reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Dated: November 30, 2019

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DOHMH v. Baila Hauer
30216-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH vs J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30216-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. Respondent was properly served the Summons

The hearing officer was correct in concluding that Respondent's father is a person of suitable age and discretion as provided in OATH Rule 6-08(b)(1)(i)(H) and that the additional mailing of the Summons satisfied OATH Rule 6-08(b)(1)(ii). Accordingly, under this Tribunal Respondent was properly served the Summons. *See Reda v. Dep't of Health*, 137 Misc. 2d 61, 62-63 (Sup. Ct. N.Y. Co. 1987), *aff'd*, 143 A.D.2d 1073 (1st Dep't 1988) (finding that though service of a violation on petitioner's father did not technically comply with the CPLR, it was sufficient as "[i]n an administrative proceeding the standard for service is whether the notice under all the circumstances is reasonably calculated to make the parties aware of the proceeding so that they have an opportunity to be heard.").

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*,

Appeals No. 10087317C (March 12, 2018) (“Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.”).

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, “Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector’s testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges the hearing officer's decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer's findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer's decision is based on the credibility of the evidence presented, the Hearing Officer's decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because Respondent alleges it is arbitrary and capricious for the hearing officer to sustain the Summons

Respondent provides no basis for their constitutional argument that this Tribunal cannot sustain a summons that requires a child under twelve months be vaccinated since the decision is arbitrary and capricious and lacks rational basis. We agree with Respondent that constitutional arguments are beyond the scope of the Tribunal (Appeal page 19, footnote 9) but the Summons does not require constitutional conclusions to be decided.

The violation in the Summons is within the jurisdiction of the Tribunal as provided in Title 48, § 6-02, which states that “the Tribunal has jurisdiction to hear and determine summonses alleging non-compliance with the provisions of the Health ... relating to or affecting health within the City and any other laws or regulations that the Department of Health and Mental Hygiene has the duty or authority to enforce.”

Accordingly, the decision should be affirmed.

VIII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation for a specified violation, as defined by paragraph (b) of subdivision 4 of this section, when dismissal is appropriate in the interest of justice, within the meaning of this subdivision”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent's appeal.

Accordingly, the decision should be affirmed.

IX. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As mentioned above, Respondent concedes in their appeal (page 19, footnote 9) that Respondent's Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

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Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>BAILA HAUER 201 HOOPER STREET BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30216-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Lorraine Peonne, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30216-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 30, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30216-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 2, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner the Department of Health and Mental Hygiene (DOHMH), May 1, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live and work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, a DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. Respondent also argued that the MMR vaccine was not licensed for children under one year of age.⁶ For this hearing, Respondent argued that the summons should be dismissed for defective service because it was not given to Respondent, but to her father at his apartment, located on a different floor from Respondent's in the same building. Respondent stated that the father told the officer that it was not Respondent's apartment and the officer replied, "I will give it to her." Two declarations made by Respondent were taken into evidence, one as to service of the summons and one stating that the child was less than one year old.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons. Petitioner argued that the Resolution was by its terms effective immediately.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ The DOHMH doctor stated that despite the licensure issue, the Advisory Committee on Immunization Practices,⁹ which sets the national standards, recommends that a dose of MMR vaccine be considered in an outbreak setting to children ages six to eleven months, and routinely to that age group prior to international travel. As to service of the summons, Petitioner stated that the summons was also mailed to Respondent.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in a hearing held earlier that day, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

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authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. The hearing officer rejected Respondent's contention that service of the summons was improper. He found that Respondent's father was a person of suitable age and discretion as provided in 48 RCNY § 6-08(b)(1)(H) and that the mailing of the summons to Respondent satisfied the service requirement of 48 RCNY § 6-08(b)(1)(ii). He credited the testimony of the DOHMH doctor that in emergency/outbreak situations, an MMR vaccine is appropriate for a child older than six months. He credited the affirmations of the IO and the allegations in the summons and found that Respondent had failed to provide a defense to the charge. The hearing officer found Respondent's Constitutional and scientific arguments to be beyond the scope of the hearing.

On appeal, Respondent repeats the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹⁰ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds. Specifically, as to this case, Respondent argues that the summons was not properly personally served on her but rather on "the tenant who lives on the first floor of [her] building."

In response, Petitioner asserts that service of the summons was proper. Petitioner repeats the arguments made at the hearing and asserts that the hearing officer correctly found that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether service of the summons was proper; (2) whether Petitioner had the authority to issue the summons on the date it was issued; (3) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (4) whether Respondent established a defense to the charge.

¹⁰ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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APPLICABLE LAW

48 RCNY § 6-08(b)(1)(ii) provides in pertinent part as follows:

(ii) Alternatively, the summons may be served by mail deposited with the U.S. Postal Service, or other mailing service, to any such person at the address of the premises that is the subject of the summons or, as may be appropriate, at the residence or business address of:

(A) the alleged violator,

.

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

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ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

* * * * *

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

* * * * *

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Per 48 RCNY § 6-08(b)(1)(ii), service of a summons may be made by mail. As there was uncontroverted testimony and documentation that the summons was mailed to Respondent, the Tribunal finds that service was proper. The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 3, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

¹¹ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was

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Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that service of the summons was proper, that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹² See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹³ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30244-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Chava Biederman ID NUMBER: 50091950

ADDRESS: 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206 PHONE: _____

DATE AND TIME OF OCCURRENCE: April 29, 2019, 12:35 PM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: June 19, 2019 AT: 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan 66 John Street 10th & 11th Floor New York, NY 10038
Staten Island 350 St. Marks Place Main Floor Staten Island, NY 10301
Bronx 3030 Third Avenue Room 250 Bronx, NY 10455
Queens 31-00 47th Avenue 3rd & 4th Floor Long Island City, NY 11435
XX Brooklyn 9 Bond Street 6th & 7th Floor Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC MC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, B.B., who is at least six months old, lives at 104 HEYWARD ST APT# 2FL, Brooklyn NY 11206, which is located in one of the affected zip codes listed in the Order. On April 29, 2019, a review of the Department's Central Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child B.B. has no record of measles immunization. Respondent has failed to vaccinate child B.B. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 104B and 104B-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice. I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Torian Easterling Signature ID 04/30/2019 Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Page 1 of 1

Print Name	Signature	Title	Date:
<p>The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.</p>			
<p>If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.</p> <p>If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.</p> <ul style="list-style-type: none"> • Online: To submit a defense online, visit www.nyc.gov/oath. • Phone: To schedule a hearing by phone, call (212) 436-0817. • Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038. <p>To present a defense in person:</p> <ul style="list-style-type: none"> • You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons. • If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below). • Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you. • If you require assistance with English, free language assistance will be provided. <p>Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.</p>			
<p>Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.</p>			
<p>OATH HEARINGS CENTERS</p> <p>Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath</p> <p>Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038 Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201 Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435 Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455 Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301</p>			

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORAIN PEONE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department Of Health And Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
60	Affidavit	8	9

PROCEEDINGS

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1 H.O. DAVID LEUNG: We're on the record.
2 Today's date is August 28, 2019. It's 2:40 in the
3 afternoon. My name is David Leung, hearing officer.
4 This is New York City Health Department Summons No.
5 30244-19L0, issued to initials C.B. The allegation
6 is a violation of New York City Health Code 3.05
7 regarding MMR vaccination. We have an attorney for
8 the Respondent C.B. What is your name?

9 MR. AARON SIRI: Aaron Siri.

10 H.O. LEUNG: Mr. Siri, do you make an
11 application regarding the record from the previous
12 recording?

13 MR. SIRI: Sure.

14 H.O. LEUNG: Previous hearing?

15 MR. SIRI: Sure. I move to have the, the
16 argument regarding the hearing officer appear, as
17 well as all the other substantive arguments,
18 objections and documents within that hearing
19 incorporated by reference into this one, as well as
20 P, P-3 from a subsequent hearing incorporated by
21 reference into this one.

22 H.O. LEUNG: Okay. And can you just put
23 the hearing number of that recording on the record?

24 MR. SIRI: 30198-19 elev-, L0.

25 H.O. LEUNG: And we have an attorney, two

PROCEEDINGS

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1 attorneys for Department of Health.

2 MR. THOMAS MERRILL: Yes, Thomas Merrill.

3 MS. LORAIN PEONE: Loraine Peone.

4 H.O. LEUNG: Thank you. Mr. Siri, do you
5 under-, do you waive need for an interpreter, do you
6 understand that the penalty for this violation is
7 \$1,000, and do you understand both sides can appeal?

8 MR. SIRI: Yes.

9 H.O. LEUNG: In the initial recording that
10 we've incorporated from 30198-19L0, you objected to
11 the non-presence of the issuing officer. I made a
12 ruling that the issuing officer was not needed for,
13 in order for you to get a fair and impartial hearing.
14 You renew that objection here; is that correct?

15 MR. SIRI: That's right.

16 H.O. LEUNG: Okay. We have a doctor also
17 here. What is your name?

18 DR. JENNIFER ROSEN: Jennifer Rosen.

19 H.O. LEUNG: Do you swear to tell the
20 truth, Dr. Rosen?

21 DR. ROSEN: Yes.

22 [WHEREUPON THE WITNESS, J E N N I F E R R
23 O S E N, WAS DULY SWORN.]

24 H.O. LEUNG: Thank you. Mr. Merrill, do
25 you have any other evidence or testimony you want to

PROCEEDINGS

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1 present other than what's on the record?

2 MR. MERRILL: No, Your Honor. I'm relying
3 on the exhibits from the other cases and on the NOV.

4 H.O. LEUNG: Mr. Siri, do you waive a
5 formal reading of the allegations?

6 MR. SIRI: I do.

7 H.O. LEUNG: Okay. Do you have anything
8 you want to add other than what the record shows?

9 MR. SIRI: Other than incorporating all the
10 other arguments, I will add that this summons has the
11 wrong floor number for my client on it. She resides
12 on the third floor, not the second floor as listed on
13 the summons. And I have one other argument after
14 we've --

15 H.O. LEUNG: Well, let me just ask you --

16 MR. SIRI: -- addressed that one.

17 H.O. LEUNG: -- this. Do you deny that
18 she, your client was served with the summons on the
19 day of issuance? I mean, by, by the inspector?

20 MR. SIRI: She was not personally served.

21 H.O. LEUNG: Okay. What's the affidavit
22 say?

23 MR. MERRILL: I have it right here. It's a
24 mail-in mail, Your Honor.

25 H.O. LEUNG: It's a mail-in mail? Okay.

PROCEEDINGS

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1 Does your client deny receiving it by mail? Service
2 by mail?

3 MR. SIRI: She does not.

4 H.O. LEUNG: So you're not challenging
5 service by mail.

6 MR. SIRI: No.

7 H.O. LEUNG: Okay.

8 MR. SIRI: But the floor, wrong.

9 H.O. LEUNG: Okay. In the previous cases,
10 you made an allegation regarding improper service.
11 Is there a timing issue? I know the posting of the
12 three days is -- what's, what's the date of issuance
13 on this?

14 MR. SIRI: Well, that, that's a separate
15 argument.

16 H.O. LEUNG: Right. I just want to make
17 sure --

18 MR. SIRI: Oh, oh, oh.

19 H.O. LEUNG: Because some cases you're not
20 bringing that argument because --

21 MR. SIRI: Oh, I'm sorry.

22 H.O. LEUNG: -- it's clearly established.

23 MR. SIRI: This one's April 29th --

24 H.O. LEUNG: Okay.

25 MR. SIRI: -- which would've been after.

PROCEEDINGS

8

1 H.O. LEUNG: So you're not making that
2 argument again.

3 MR. SIRI: So I'm making the argument that
4 the, you know, this is only alleging a violation of
5 the Order, which expired on April 17th --

6 H.O. LEUNG: Right.

7 MR. SIRI: -- I'm making that, and
8 obviously I'm making all the other arguments.

9 H.O. LEUNG: Right.

10 MR. SIRI: As well, I'm adding a, you know,
11 a defect on the summons that the floor number is
12 wrong and, you know, that, that it's not the correct
13 address for the Respondent.

14 H.O. LEUNG: Okay.

15 MR. SIRI: And I've got another argument if
16 we're done with that one.

17 H.O. LEUNG: Yes.

18 MR. SIRI: Okay. And then the other
19 argument is that this violation alleges that it
20 occurred at a specific address at a specific date and
21 time, and there was no violation at that address at
22 that date and time because my client wasn't residing
23 there. And I've got an affidavit to that effect.

24 H.O. LEUNG: And not residing in a sense
25 that they had the wrong floor number?

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1 MR. SIRI: Not --

2 H.O. LEUNG: Is that what you're alleging?

3 MR. SIRI: Yeah. I mean, she wasn't there.

4 So if, you know, you're, you're saying that she, at
5 the date and time at that a- at that, at that place
6 she was in violation, she wasn't.

7 H.O. LEUNG: Okay, I'm going to mark this
8 as Respondent's 60, six-zero. Any objection to it,
9 its admission?

10 MR. MERRILL: No, Your Honor, no objection
11 to its admission.

12 H.O. LEUNG: Okay, R-60's admitted.

13 **[Respondent's Exhibit 60 admitted into**
14 **evidence.]**

15 H.O. LEUNG: I'm going to turn to
16 Department of Health to address the two arguments
17 supplemented by Mr. Siri. The first one is that the
18 summons has the wrong floor number and therefore it
19 should be dismissed, and second is that the
20 occurrence -- well, the argument made in, you know,
21 Respondent's 60.

22 MR. MERRILL: I don't believe that the, the
23 floor is material to the violation, Your Honor. The
24 Order says you can't be [unintelligible] [00:04:52],
25 so if you've got the wrong floor, and I don't know if

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1 we do or not, that doesn't change the fact that you
2 were, you know, at Hayward Street or in Brooklyn.
3 That's the material element, and she got the, the NOV
4 came to her at that address, so if she's on a
5 different floor it doesn't matter that we
6 [unintelligible] [00:05:08] number for the purposes
7 of violating the Order.

8 H.O. LEUNG: Okay. And the subsequent
9 argument that, that's listed in Respondent's 60? You
10 want to address that?

11 MR. MERRILL: I thought that was the one I
12 did, but I'm [unintelligible] [00:05:21] --

13 H.O. LEUNG: Oh, is it?

14 MR. MERRILL: Sixty, yes.

15 H.O. LEUNG: Oh, I guess it's the same
16 argument.

17 MR. MERRILL: Yeah.

18 H.O. LEUNG: Because they're saying the
19 address is incorrect and therefore it's a factual
20 impossibility for the, for the allegation to be
21 committed because --

22 MR. MERRILL: Correct. And I'm saying that
23 the material --

24 H.O. LEUNG: -- it doesn't --

25 MR. MERRILL: -- the material element is

PROCEEDINGS

11

1 being in Brooklyn, so it's not, it's not necessary,
2 it's not material that it be on a specific floor.

3 H.O. LEUNG: Mr. Siri, you want to address
4 his [unintelligible] [00:05:41]

5 MR. SIRI: Yeah, and my response to that is
6 that's a different violation. If he wants to issue
7 that violation, he can do it at a different time.
8 That's not this violation.

9 H.O. LEUNG: Okay. I have enough to make a
10 decision. Hearing nothing further, this hearing is
11 closed. Thank you.

12 [END OF HEARING]

13

14

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Mental Health and Hygiene v. Chava Biederman on August 28, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC.

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>CHAVA BIEDERMAN 104 HEYWARD STREET, 2ND FLOOR BROOKLYN, NY 11206</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30244-19L0</u></p> <p>Decision Date: <u>8/30/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Lorraine Peonne, Esq. and Dr. Jennifer Rosen, MD.</u></p> <p>Type of Hearing: <u>In Person</u></p>
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Summary Disposition: **Sustained**

LINE ITEM	VIOL CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on April 29, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

Debra

				<p>in Williamsburg, Brooklyn, which included zip code 11206 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of April 29, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order. In support of his argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments are beyond the scope of the hearing.</p>		
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				<p>and as such, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent stated that the address of occurrence is incorrect in that it lists the wrong floor number. (See R's 60, affidavit of Respondent). I find that the floor number listed on the summons, even if incorrect, did not affect Respondent's right to notice of the violation or to receive a fair hearing.</p> <p>I credit the testimony of the issuing inspector and the allegations contained in the summons and find that they support a violation of the cited section of law. I find that respondent failed to provide a defense to the allegations. This fine item is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

Dell...

IF YOU ARE FOUND IN VIOLATION, YOU MUST PAY THE PENALTY WITHIN 30 DAYS OF THE DECISION DATE OR 35 DAYS IF MAILED.

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

IF YOU DISAGREE WITH THE DECISION, YOU MAY APPEAL IT

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

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If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

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GNDc Decision Back Heath 5-6-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Chava Biederman

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30244-19L0

NOTICE OF APPEAL

Respondent Chava Biederman (“Mrs. Biederman”) hereby appeals the decision on Summons Number 30244-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On September 30, 2019, Mrs. Biederman submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on October 9, 2019, and set the deadline to file this appeal for Tuesday, November 12, 2019. Mrs. Biederman submitted a second *Request for Extension of Time to File Appeal* on November 7, 2019. OATH approved the second request on November 12, 2019, and set the deadline to appeal for December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On April 30, 2019, Mrs. Biederman was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child B.B. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mrs. Biederman of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On April 30, 2019 Mrs. Biederman was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On August 28, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated August 30, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Biederman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on April 30, 2019, alleges a violation that occurred on April 29, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Biederman alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Biederman violated the Commissioner’s Order on April 29, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was April 29, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE MRS. BIEDERMAN WAS NOT PRESENT AT THE PLACE OF OCCURRENCE ON THE DATE OF OCCURRENCE, AND THEREFORE NO VIOLATION EXISTED AS ALLEGED

The Tribunal should dismiss the Summons because Mrs. Biederman does not reside at the address listed on the Summons as the "Place of Occurrence" and Mrs. Biederman was not present at the "Place of Occurrence" when the alleged violation took place on April 29, 2019. Mrs. Biederman presented sufficient and reliable evidence at the hearing that she did not live or reside at the "Place of Occurrence" as listed on the Summons and was not present at that location on the time and date of occurrence. **Respondent-Appellant's Hearing Exhibit 60, Declaration of**

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

Chava Biederman; Exhibit C, Part C, Hearing Transcript p 5-7. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because no violation existed as alleged, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. BIEDERMAN AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Biederman. Due process requires that Mrs. Biederman be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Biederman be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip

codes.”⁷ **Petitioner-Appellee’s Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner’s Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Biederman from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The “Details of Violation” of the Summons, as sworn to by the issuing officer, refer to both the Commissioner’s Order and the Resolution as *two distinct orders*. This section states that the Commissioner’s Order required “all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles.” **Exhibit A, Summons.** This representation of the Commissioner’s Order is incorrect. The Commissioner’s Order did not include individuals who attend school in the affected zip codes but did include people who “reside” in the affected zip codes - which the Summons fails to include. **Petitioner-Appellee’s Hearing Exhibit 1.**

Finally, the “Details of Violation” section of the sworn Summons summarizes the Resolution as requiring vaccination, “unless they demonstrate proof of immunity or that immunization is not *medically appropriate*.” **Exhibit A, Summons.** (emphasis added.) However, the Commissioner’s Order and the Resolution both state that Mrs. Biederman must demonstrate a “medical exemption.” From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Biederman is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee’s definition of a “medical exemption” to the MMR vaccine).

⁷ “RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside**, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare.” **Petitioner-Appellee’s Hearing Exhibit 2.** (emphasis added.) The distinction between the words “live” and “reside” are legally significant. *See, argument at Section I, p 5.*

These ambiguous and conflicting statements confuse the standard and deprived Mrs. Biederman of mounting a viable defense to the Summons. Furthermore, Mrs. Biederman was clearly not provided “an accurate statement of the matter to be adjudicated” as required by NYCC § 1046.

In sum, the Commissioner’s Order and the Board’s Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Biederman an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. BIEDERMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Biederman of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Biederman proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Biederman’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-

Appellee, Dr. Jennifer Rosen ("Dr. Rosen"), was available and could answer any questions regarding these disputed facts. Exhibit C, Hearing Transcript, p 14. However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (Exhibit C, Hearing Transcript, p 107); did not know where the child's address was obtained (Exhibit C, Hearing Transcript, p 109); did not know if the child had any medical contraindication to MMR before the Summons was issued (Hearing Transcript, p 117); and did not know if any person from the health department had contacted Mrs. Biederman to determine if the child had been given MMR before the Summons was issued (Hearing Transcript, p 117-118).⁶

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Biederman the ability to cross-examine the issuing officer and deprive Mrs. Biederman of a full and fair hearing, and the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. BIEDERMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Biederman of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Biederman's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. Exhibit C, Hearing Transcript, pp 131-133; 240.

⁶ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Biederman's hearing. Exhibit C, Hearing Transcript, pp 142-143; 241-242.

In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Biederman's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Biederman of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Biederman "*relied upon* the last paragraph of the Order, which states, '[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board'" to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Biederman did not *rely upon* this statement made in the Commissioner's Order. Instead, Mrs. Biederman's argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner's Order. In fact, counsel for Mrs. Biederman read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Biederman paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Biederman made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer's authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Biederman made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states "medically appropriate" as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the "April 17, 2019 Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order." **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner's Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner's Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer's finding that the Commissioner's "exercise of authority" was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Biederman as having violated the Commissioner's written order, not the Commissioner's exercise of

emergency authority. Therefore, the Hearing Officer's finding that the Board continued the Commissioner's exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer's decision lacked a rational basis and is not factually supported; hence, Mrs. Biederman was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine ("IOM"), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 - *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 - CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 - NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 - Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 - NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 - Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 - Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 - American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 - Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 - PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly

elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history

of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VIII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Biederman reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;

⁹ “Respondent’s Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal.” *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

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Attorneys for Respondent-Appellant

DOHMH v. Chava Biederman
30244-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30244-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of the Resolution is applied to the Summons, the Respondent will still be found in violation since

Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The defect in the Summons's floor number does not require the Summons to be dismissed

The hearing officer was correct in finding that Respondent received notice of the violation and fair hearing even if there was a defect in the floor number on the Summons. Respondent does not contest that she was served by mail, that she did receive the Summons and resides in Brooklyn in the affected zip codes. She argues instead that no violation occurred because she lives on a different apartment floor than the one listed on the Summons. However, Respondent fails to show how the defect prejudiced her in any way and in the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017).

Moreover, in an administrative setting like the Tribunal, Respondent can be properly served the Summons even if there a minor defect. *See Reda v. Dep't of Health*, 137 Misc. 2d 61, 62-63 (Sup. Ct. N.Y. Co. 1987), *aff'd*, 143 A.D.2d 1073 (1st Dep't 1988) (though service of a violation did not comply with the CPLR, it was sufficient as "[i]n an administrative proceeding the standard for service is whether the notice under all the circumstances is reasonably calculated to make the parties aware of the proceeding so that they have an opportunity to be heard."); *See Nole v. NYC Dep't of Housing Preservation & Development*, 26 A.D.3d 163, 164 (1st Dep't 2006) (disregarding error in notice as "no one was prejudiced by this mistake").

Accordingly, the decision should be affirmed.

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted." The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the

allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges the hearing officer's decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that "the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law."

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer's findings, however, that is not grounds to reverse the decision. It has been held that "[w]here evidence conflicts and a Hearing Officer's decision is based on the credibility of the evidence presented, the Hearing Officer's decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance." *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) ("...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*") (emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent's appeal.

Accordingly, the decision should be affirmed.

VIII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent's Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>CHAVA BIEDERMAN 104 HEYWARD STREET, 2ND FLOOR BROOKLYN, NY 11206</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30244-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Lorraine Peonne, Esq. and Dr. Jennifer Rosen, MD.</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

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Appeal No. 30244-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated August 30, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30216-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on April 30, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on April 29, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on August 28, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Appeal No. 30244-19L0

DOHMH v. J. Doe

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emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent asserted that the summons incorrectly showed Respondent's apartment as being on the second floor of the building instead the third; Respondent argued that a charge that she was in violation at that time in that place was an impossibility as she was not in that place. Respondent did not deny receipt of the summons by mail.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons, and that the Resolution was by its terms effective immediately.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁷ In response to Respondent's assertion that the summons showed the wrong floor for Respondent's residence, Petitioner argued that for the purposes of this summons, the floor was not material to the violation, that the material element for violating the Order was that the apartment was in Brooklyn, as alleged.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. The hearing officer found that the floor number listed in the summons, even if incorrect, did not affect Respondent's right to notice of the violation or to receive a fair hearing. He found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. The hearing officer credited the testimony and allegations contained in the summons. He found that they supported a violation of the cited section and that Respondent failed to provide a defense to the allegations.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

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On appeal, Respondent repeats the arguments raised in Docket No. 30198-19L0, relevant to this and other cases, regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds. Specifically, as to this case, Respondent argues that the summons must be dismissed because Respondent was not present and did not reside at the alleged place of occurrence at the time of the alleged violation, an apparent reference to the floor number indicated on the summons.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0 and those made at the hearing. Petitioner asserts that the hearing officer was correct in finding that the Commissioner's Order was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power asserted in the Order, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient. Specifically, as to this summons, Petitioner asserts that the hearing officer was correct in finding that Respondent received notice of the violation and a fair hearing even if there was a defect in the floor number on the summons. Petitioner notes that Respondent did not contest receipt of service by mail or that she resides in an affected ZIP code. Citing *TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017), Petitioner argues that absent any demonstrated prejudice, dismissal based on notice is not warranted. Petitioner also argues that the standard for service in an administrative proceeding was met: "whether the notice under all the circumstances was reasonably calculated to make the parties aware of the proceeding so that they have an opportunity to be heard."¹⁰

ISSUES ON APPEAL

The issues on appeal are (1) whether misidentifying the floor location of Respondent's apartment in the summons required that the summons be dismissed; (2) whether Petitioner had the authority to issue the summons on the date it was issued; (3) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

⁹ "MMR" stands for Measles, Mumps, Rubella.

¹⁰ See *Reda v. Dep't of Health*, 137 Misc.2d 61, 62-63 (Sup. Ct. N.Y. Co. 1987), aff'd, 143 A.D.2d 1073 (1st Dep't 1988)

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nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.....

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.....

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

Petitioner is correct that the floor location of Respondent's apartment was not material to the charge. As Petitioner established Respondent's residence in one of the subject ZIP codes, and service by mail was not denied, the hearing officer properly did not dismiss the summons because of a possible error in the floor number.

The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months of age who was living in designated ZIP codes in Brooklyn and who was not vaccinated against measles should cause the child to be vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on April 29, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

¹¹ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY S 6-08(c)(2), I part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in

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produce the IO for cross-examination; and (4) whether Respondent established a defense to the charge.

APPLICABLE LAW

48 RCNY § 6-08(b)(1)(ii) provides in pertinent part as follows:

(ii) Alternatively, the summons may be served by mail deposited with the U.S. Postal Service, or other mailing service, to any such person at the address of the premises that is the subject of the summons or, as may be appropriate, at the residence or business address of:

(A) the alleged violator,

.

HC § 3.05(a) provides as follows: “No person shall violate an order of the Board, Commissioner or Department.”

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the

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Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal. The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. See *NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007).

In view of the foregoing, the Tribunal finds that an error in the summons stating the wrong floor location for Respondent's apartment did not require dismissal of the summons, that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirement of 48 RCNY S 6-08(c).

¹² See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). (After admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement.)

¹³ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (There is a limited due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden of producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test.)

SUMMONS NUMBER: 30422-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Rachel Guttman ID NUMBER: 50094292

ADDRESS: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205 PHONE:

DATE AND TIME OF OCCURRENCE: June 13, 2019 AT 1:38 PM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: August 1, 2019 AT 9:00 AM

**** RESPONDENT MUST APPEAR IN PERSON ****

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

Manhattan
66 John Street
10th & 11th Floor
New York, NY 10038

Staten Island
350 St. Marks Place
Main Floor
Staten Island, NY 10301

Bronx
3030 Third Avenue
Room 250
Bronx, NY 10455

Queens
31-00 47th Avenue
3rd & 4th Floor
Long Island City, NY 11435

Brooklyn
9 Bond Street
6th & 7th Floor
Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, E.G., who is at least six months old, lives at: 79 Skillman Street, Apt. 4A, Brooklyn, N.Y. 11205, which is located in one of the affected zip codes listed in the Order. On June 13, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child E.G. has no record of measles immunization. Respondent has failed to vaccinate child E.G. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Gerald Cohen

06/14/2019

Print Name

Signature

ID

Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by:

Print Name

Signature

Title

Date:

Σ 13

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,
 Petitioner,

Index No.
30422-19L0

- against -

RACHEL GUTTMAN,
 Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORAIN PEONNE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department Of Health & Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

INDEX

PETITIONER'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

RESPONDENT'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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PROCEEDINGS

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1 H.O. DAVID LEUNG: We are on the record.
2 It's September 25, 2019, 10:32 in the morning. We
3 are here today on the Health Department MMR related
4 summons number 30422-19L0 issued to Rachel Guttman.
5 We have attorneys from the Department of Health here.
6 Can you state your name for the record, please?
7 MR. THOMAS MERRILL: That's Thomas Merrill.
8 MS. LORAIN PEONE: Loraine Peonne.
9 H.O. LEUNG: And we also have a physician
10 from the Department of Health here?
11 DR. JENNIFER ROSEN: Jennifer Rosen.
12 H.O. LEUNG: Dr. Rosen, do you swear or
13 affirm the testimony you give will be the truth?
14 MS. ROSEN: Yes.
15 [WHEREUPON THE WITNESS, J E N N I F E R R
16 O S E N, WAS DULY SWORN.]
17 H.O. LEUNG: Thank you. Mr. Si-, Siri, can
18 you put your name on the record?
19 MR. AARON SIRI: Sure. Aaron Siri for the
20 respondent.
21 H.O. LEUNG: Mr. Siri, do you waive
22 translation, the need to have the issuing -- well, do
23 you waive translation and do you understand both
24 sides have the right to appeal and the penalty for
25 the cited violation is \$1,000?

PROCEEDINGS

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1 MR. SIRI: I do, Your Honor, and I waive a
2 reading.

3 H.O. LEUNG: Great. And you have
4 previously put on the record your objection or your
5 request to have the issuing officer appear and you
6 also made various arguments and introduced various
7 documents under a previously held summons num-
8 hearing 30198-1910. Is that correct?

9 MR. SIRI: That's right.

10 H.O. LEUNG: And you incorporate all the
11 arguments and evidence that you presented under that
12 hearing?

13 MR. SIRI: I do, Your Honor.

14 H.O. LEUNG: Okay. Any objection from the
15 Department of Health?

16 MR. MERRILL: No, Your Honor.

17 H.O. LEUNG: Okay. Since we are waiving a
18 reading of the summons, I'm going to turn to
19 Department of Health and ask what, if anything, you
20 want to add into the evidence.

21 MR. MERRILL: Your Honor, the resolution
22 and the, the Board and the Commissioner's order were
23 put in, in the, in the previous hearing the last
24 time, last time we were here. I just -- I'm, I'm
25 relying on the NOV that alleges that on June 13th, we

PROCEEDINGS

6

1 checked the CIR, despite the order and the resolution
2 issued back in April, CIR, I'm sorry, CIR. The, the,
3 the child had not been immunized and was in Brooklyn
4 in violation of the order.

5 H.O. LEUNG: Mr. Siri?

6 MR. SIRI: Your Honor, we rest our
7 arguments and defenses from 30198-19L0.

8 H.O. LEUNG: Okay. I have enough to make a
9 decision. Hearing nothing further, each side will
10 receive a written decision within 30 days. Thank
11 you.

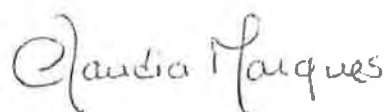
12 [END OF HEARING]

13

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health & Mental Hygiene v. Rachel Guttman on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By



Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>RACHEL GUTTMAN 79 SKILLMAN STREET, APT. 4A BROOKLYN, NY 11205</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30422-19L0</u></p> <p>Decision Date: <u>9/25/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
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Summary Disposition: **Sustained**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on June 13, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

D. J. Lee

			<p>in Williamsburg, Brooklyn, which included zip code 11205 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of June 13, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
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Dell...

				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>Petitioner relied upon the allegations contained in the summons. Other than the above-stated arguments, Respondent did not make any additional arguments.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00



IF YOU ARE FOUND IN VIOLATION, YOU MUST PAY THE PENALTY WITHIN 30 DAYS OF THE DECISION DATE OR 35 DAYS IF MAILED.

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

IF YOU DISAGREE WITH THE DECISION, YOU MAY APPEAL IT

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

APPEAL BY ENFORCEMENT AGENCY

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
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or call 1-844-OATH-NYC

GN3c Decision Back Health 5-9-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Rachel Guttman

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30422-19L0

NOTICE OF APPEAL

Respondent Rachel Guttman ("Mrs. Guttman") hereby appeals the decision on Summons Number 30422-19L0 (the "Summons").¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the "Commissioner") issued an Order (the "Commissioner's Order") requiring that certain categories of people in certain zip codes be injected with Merck's product M-M-R-II, also known as the measles, mumps, rubella ("MMR"), within forty-eight hours of the Commissioner's Order. **Petitioner-Appellee's Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the "Board") created a resolution (the "Resolution") which also required administration of the MMR vaccine, but defined what constituted a "nuisance" completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mrs. Guttman submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On June 14, 2019, Mrs. Guttman was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child E.G. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summon should have been dismissed and that the Hearing Officer deprived Mrs. Guttman of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On June 14, 2019 Mrs. Guttman was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Guttman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on June 14, 2019, alleges a violation that occurred on June 13, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Guttman alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Guttman violated the Commissioner’s Order on June 13, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was June 13, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. GUTTMAN AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Guttman. Due process requires that Mrs. Guttman be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached)

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." Petitioner-Appellee's Hearing Exhibit 2.

failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Guttman be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Guttman from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. See, argument at Section I, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Guttman must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Guttman is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Guttman of mounting a viable defense to the Summons. Furthermore, Mrs. Guttman was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Guttman an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. GUTTMAN OF A FULL AND FAIR HEARING BY

**REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER
WHERE A DISPUTE OF FACT WAS PRESENTED**

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Guttman of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Guttman proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Guttman’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“Dr. Rosen”), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child’s address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Guttman to determine if the child had been given MMR before the Summons

was issued (Hearing Transcript, p 117-118).⁵

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Guttman the ability to cross-examine the issuing officer and deprive Mrs. Guttman of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. GUTTMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Guttman of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Guttman's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Guttman's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Guttman of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁵ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Guttman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Guttman “*relied upon* the last paragraph of the Order, which states, “[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board”” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Guttman did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mrs. Guttman’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mrs. Guttman read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Guttman paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Guttman made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Guttman made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this

conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Guttman as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mrs. Guttman was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Guttman reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Dated: November 30, 2019

SIRI & GLIMSTAD LLP



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200 Park Avenue
17th Floor
New York, New York 10166
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Attorneys for Respondent-Appellant

DOHMH v. Rachel Guttman
30422-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30422-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

III. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a

fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

V. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VI. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section,* when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>RACHEL GUTTMAN 79 SKILLMAN STREET, APT. 4A BROOKLYN, NY 11205</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30422-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
New York, NY 10038
Telephone: (212) 436-0624
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Appeal No. 30422-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30422-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on June 14, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 13, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁷ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. The hearing officer found that the allegations in the summons supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time

⁹ "MMR" stands for Measles, Mumps, Rubella.

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period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's

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records that took place on June 13, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30376-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: ASCHER BERKOWITZ ID NUMBER: 50093815

ADDRESS: 95 SKILLMAN ST #4C BROOKLYN, NY 11205 PHONE:

DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:30 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE: 95 SKILLMAN ST #4C BROOKLYN, NY 11205

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 24, 2019 AT 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan Staten Island Bronx Queens XX Brooklyn
66 John Street 350 St. Marks Place 3030 Third Avenue 31-00 47th Avenue 9 Bond Street
10th & 11th Floor Main Floor Room 250 3rd & 4th Floor 6th & 7th Floor
New York, NY 10038 Staten Island, NY 10301 Bronx, NY 10455 Long Island City, NY 11435 Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, Z.B., who is at least six months old, lives at: 95 SKILLMAN ST #4C BROOKLYN, NY 11205, which is located in one of the affected zip codes listed in the Order. On June 4, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child Z.B. has no record of measles immunization. Respondent has failed to vaccinate child Z.B. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 104B and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Handwritten signature of Pooja Jani

Pooja Jani Signature 06/04/2019 Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Received by: Print Name Signature Title Date

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
 Petitioner,

Summons No.
30376-19L0

- against -

ASCHER BERKOWITZ,
 Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORAIN PEONE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department Of Health And Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
79	Note From Mother	6	7

PROCEEDINGS

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1 H.O. DAVID LEUNG: Okay, we're on the
2 record. It's September 25, 2019, 10:35 in the
3 morning. We're at the Brooklyn OATH location. My
4 name's Dave Leung, hearing officer. We're here today
5 on Summons No. 30376-19L0, issued by the Health
6 Department regarding an MMR vaccination issued to
7 Ascher Berkowitz. We have attorneys from the
8 Department of Health here. Can you state your name
9 for the record?

10 MR. THOMAS MERRILL: Thomas Merrill.

11 MS. LORAIN PEONE: Loraine Peone.

12 H.O. LEUNG: We also have a physician from
13 the Department of Health here.

14 DR. JENNIFER ROSEN: Jennifer Rosen.

15 H.O. LEUNG: Dr. Rosen, do you swear or
16 affirm the testimony you give will be the truth?

17 DR. ROSEN: Yes.

18 [WHEREUPON THE WITNESS, J E N N I F E R R
19 O S E N, WAS DULY SWORN.]

20 H.O. LEUNG: Thank you. And we have an
21 attorney for the Respondent here. Mr. Siri?

22 MR. AARON SIRI: Aaron Siri on behalf of
23 Respondent.

24 H.O. LEUNG: And, Mr. Siri, do you waive
25 translation and do you understand both sides have the

PROCEEDINGS

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1 right to appeal and that the cited section of law
2 carries a penalty of \$1,000?

3 MR. SIRI: I do, and I waive a reading of
4 the violation.

5 H.O. LEUNG: Okay. In the previously-held
6 summons, hearing, excuse me, under Summons No. 30198-
7 19L0, you made a request to have the issuing officer
8 appear. I denied your request. Do you incorporate
9 the same arguments for that request here in this
10 hearing?

11 MR. SIRI: I do.

12 H.O. LEUNG: And you also submitted
13 documents and made some Constitutional arguments
14 under that previous hearing. Do you incorporate all
15 the evidence you provided and all the arguments you
16 provided under that previous hearing and bring it
17 forth, bring it forth here?

18 MR. SIRI: I do. I incorporate all the
19 evidence and the arguments, including the non-
20 Constitutional arguments as well as the
21 Constitutional ones.

22 H.O. LEUNG: Great. Since you've waived
23 the formal reading of the summons, I'm going to turn
24 immediately to the Department of Health and ask them
25 what evidence they have pertaining to this summons.

PROCEEDINGS

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1 MR. MERRILL: Your Honor, the Resolution
2 and the Order of the Commissioner were put into
3 evidence in the consolidated record we have from the
4 prior date. I'm going to rest on the NOV. This is,
5 again, a checkup of the immunization registry on June
6 4th. It showed that this child was in Brooklyn in
7 violation of the Order, having not been vaccinated
8 despite the Orders back in April.

9 H.O. LEUNG: Mr. Siri?

10 MR. SIRI: In -- the only additional
11 defense, Your Honor, we'd like to present is a
12 Declaration from the mother. The -- on June 4, 2019,
13 the child was healing from eye surgery. The child
14 also had to, had a previous reaction to a vaccine and
15 upon advice of the pediatrician decided to delay the
16 vaccination of the MMR until the child's eye was
17 fully healed. The pediatrician has indicated they
18 are, while they're happy to have provided that, made
19 that decision for the parent at the time, they are
20 fearful of the Department of Health's reaction to
21 them writing anything that says the child shouldn't
22 get a vaccine and what consequences the pediatrician
23 might face from the Department of Health, so the
24 doctor wouldn't give a note. But -- with the details
25 I just relayed. But the mother did.

PROCEEDINGS

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1 H.O. LEUNG: Okay. I'm going to mark that
2 as Respondent's 79. The Department of Health, any
3 objection to that coming into the record?

4 MR. MERRILL: No objection to it coming
5 into the record, Your Honor.

6 **[Respondent's Exhibit 79 admitted into**
7 **evidence.]**

8 H.O. LEUNG: And your response to the
9 affidavit and arguments in there?

10 MR. MERRILL: My response is again, you
11 know, although the child was not vaccinated on June
12 4th, it may or may not have been recovering from eye
13 surgery that prevented the child to be vaccinated on
14 that day or while he heals. I would just point out
15 that again the child had ample, the parent had ample
16 opportunity from April to bring the child in to be
17 vaccinated to be compliant on June 4th and they
18 failed to do that. Regarding the pediatrician,
19 without getting into whether that's true or not, I
20 would just point out that under State law, again for
21 a school -- and I know that this is not a school
22 case, but I would point out that medical exemptions,
23 by State law, require a doctor's note. So for the --
24 and I'll give you a cite on that, Your Honor. It's
25 10 NYC RR 66-1.3. So despite this pediatrician, this

PROCEEDINGS

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1 parent may say this pediatrician's -- I'm having a
2 senior moment here [unintelligible] [00:04:09] --
3 paranoid, the fact of the matter is pediatricians
4 have to give notes. And I would also point out that
5 we, in fact, withdrew a case yesterday because doctor
6 -- the last time we were on, a parent had, a
7 pediatrician had indicated the child might have an
8 exemption and we contacted that pediatrician and
9 agreed to withdraw the case yesterday. So if the
10 pedia-, so I don't think -- 1. there has to be a
11 note; 2. even if there is, was a valid excuse on that
12 day, the child had ample opportunity; and 3. what is
13 it?

14 DR. ROSEN: Well, I want to clarify. This
15 is not at all a contraindication to vaccination, and
16 that's why this provider would not have written a
17 note. Because under no circumstances would the child
18 not be able to get vaccinated for having eye surgery.
19 There are national standards for what are appropriate
20 medical contraindications to vaccination, and this is
21 in no, no way a contraindication to vaccination.
22 We've had many situations where providers say parents
23 don't want to vaccinate. If a provider doesn't write
24 a note, it's because they, they don't feel
25 comfortable saying that there's a contraindication to

PROCEEDINGS

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1 vaccination.

2 MR. SIRI: I'll argue that that, the last
3 statement is speculation. Isn't it true that a, a
4 moderate illness or medical condition is a precaution
5 to giving the measles vaccine?

6 DR. ROSEN: It would be an acute illness,
7 not a surgery. Surgery is not at all a
8 contraindication. So if, if the child had an
9 immunocompromising condition, for example they were
10 on, they were on chemotherapy for cancer. This is
11 not at all a remote contraindication to vaccination.

12 MR. SIRI: Right. But a precaution is
13 different than a contraindication, correct?

14 DR. ROSEN: This is not -- eye surgery is
15 not considered moderate acute illness for the purpose
16 of not vaccinating.

17 MR. SIRI: But the CDC guidelines for
18 precautions don't say moderate acute illness; they
19 just say moderate, correct?

20 DR. ROSEN: Recovering from eye surgery is
21 not, would not be criteria for --

22 MR. SIRI: I just want to clarify --

23 DR. ROSEN: -- a moderate illness.

24 MR. SIRI: -- she said moderate acute.

25 H.O. LEUNG: Okay, I'm going to pretty end

PROCEEDINGS

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1 because I don't -- I understand her position, I
2 understand your position.

3 MR. SIRI: Sure.

4 H.O. LEUNG: I'm going to just ask you, Mr.
5 Siri, how do you respond to their argument that this
6 Order was issued -- when, when does the Department
7 [unintelligible] [00:06:20] allege this Order was in
8 effect? Just remind me.

9 MR. MERRILL: This, the Order --

10 H.O. LEUNG: [unintelligible] [00:06:23]
11 sign on April 9th and then --

12 MR. MERRILL: The, the --

13 H.O. LEUNG: -- April 12th?

14 MR. MERRILL: The Commissioner's Order came
15 on -- it's in the NOV. The Order of the Commissioner
16 was April 9th, and that's when, you know, you've got
17 48 hours. The Board Resolution was April 17th.

18 H.O. LEUNG: Okay. How do you address the

19 --

20 MR. SIRI: Yeah, I --

21 H.O. LEUNG: -- issue that your affidavit --
22 - if I do make a finding that there is a medical
23 exemption, how do you address the fact that from the
24 date that the Commissioner's Order or the Board's
25 Resolution was effective, which is April 9th or April

PROCEEDINGS

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1 17th, whatever, pick whatever date you want -- we're
2 talk-, your affidavit only covers June 4th. How do
3 you account for the time between the two or three-
4 week period between --

5 MR. SIRI: My experience, the violation
6 needs to be adjudicated as alleged. I mean, I've
7 never -- admittedly, I've dealt mostly with
8 Department of Buildings violations, but when you give
9 a violation you have a date that, you know, that you
10 allege the violation occurred. That's the date
11 you're adjudicating. I mean, how, how --

12 H.O. LEUNG: I understand.

13 MR. SIRI: It's, it's as alleged. That's
14 what they chose to allege, that's the date they chose
15 to allege. It was their choice. If they want to
16 issue a violation, Your Honor, for June 2nd, they can
17 do that. They have the power to do that.

18 H.O. LEUNG: Okay, do you have a response,
19 Department of Health?

20 MR. MERRILL: Again, the allegation is yes,
21 the person was unvaccinated on that date, but the,
22 the net result was the consequence of action all the
23 way from April and whatever. The point of fact is,
24 the, you know, , it's, it's not that you had to go
25 out and get vaccinated on that date, it's that you

PROCEEDINGS

12

1 were in, that we happened to catch you on that date
2 being unvaccinated, having thus violated the Order
3 that had required you to get vaccinated. There was,
4 again, plenty of opportunity to get vaccinated.

5 H.O. LEUNG: Mr. Siri, do you know when
6 your client's child had eye surgery? I know you say

7 --

8 MR. SIRI: Yeah.

9 H.O. LEUNG: -- the allegation here is that

10 --

11 MR. SIRI: No.

12 H.O. LEUNG: You don't.

13 MR. SIRI: I'm sorry. We don't.

14 H.O. LEUNG: Okay. Alright. I have enough
15 to make a decision. Is there anything else either
16 side wants to put in? Hearing nothing further, this
17 hearing is closed. Each side will receive my written
18 decision within 30 days. Thank you.

19 [END OF HEARING]

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CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Mental Health and Hygiene v. Ascher Berkowitz on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By



Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC.

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>ASCHER BERKOWITZ 95 SKILLMAN STREET, #4C BROOKLYN, NY 11205</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30376-19L0</u></p> <p>Decision Date: <u>9/25/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
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Summary Disposition: Sustained

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on June 4, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

Dell'Es

			<p>in Williamsburg, Brooklyn, which included zip code 11205 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of June 4, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
--	--	--	--	--	--

				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent provided an affidavit from Respondent, stating that the child was recovering from eye surgery on the date of issuance, and was advised by the pediatrician to delay vaccination. (R79) Petitioner argued that in order to establish a medical exemption, a doctor's note is required. I credit Petitioner's testimony and argument and find that Respondent did not meet its burden in showing a medical exemption because a doctor's note was not provided by Respondent. I find that Respondent's affidavit could have been supported with a doctor's note or medical records showing that the child had recent eye surgery.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

Dell...

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division **within 30 days** of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received **within 30 days** of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
see OATH's website nyc.gov/oath
or call 1-844-OATH-NYC

GACe Decision Back Health 5-5-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Ascher Berkowitz

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30376-19L0

NOTICE OF APPEAL

Respondent Ascher Berkowitz (“Mr. Berkowitz”) hereby appeals the decision on Summons Number 30376-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mr. Berkowitz submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On June 4, 2019, Mr. Berkowitz was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for his child Z.B. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mr. Berkowitz of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On June 4, 2019 Mr. Berkowitz was cited as having violated the Commissioner's Order by failing to vaccinate his child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mr. Berkowitz's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on June 4, 2019, alleges a violation that occurred on June 4, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mr. Berkowitz alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mr. Berkowitz violated the Commissioner’s Order on June 4, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[]" or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously; occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, available at <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was June 4, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MR. BERKOWITZ AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mr. Berkowitz. Due process requires that Mr. Berkowitz be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached)

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." Petitioner-Appellee's Hearing Exhibit 2.

failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mr. Berkowitz be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mr. Berkowitz from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside, work** or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. *See*, argument at Section I, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mr. Berkowitz must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mr. Berkowitz is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mr. Berkowitz of mounting a viable defense to the Summons. Furthermore, Mr. Berkowitz was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mr. Berkowitz an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. BERKOWITZ OF A FULL AND FAIR HEARING BY

**REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER
WHERE A DISPUTE OF FACT WAS PRESENTED**

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Berkowitz of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mr. Berkowitz proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mr. Berkowitz’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“**Dr. Rosen**”), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child’s address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mr. Berkowitz to determine if the child had been given MMR before the Summons

was issued (Hearing Transcript, p 117-118).⁵

Thus, it was an error of law for the Hearing Officer to refuse Mr. Berkowitz the ability to cross-examine the issuing officer and deprive Mr. Berkowitz of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. BERKOWITZ OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Berkowitz of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mr. Berkowitz's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mr. Berkowitz's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mr. Berkowitz of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁵ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mr. Berkowitz's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mr. Berkowitz “*relied upon* the last paragraph of the Order, which states, “[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board”” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mr. Berkowitz did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mr. Berkowitz’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mr. Berkowitz read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mr. Berkowitz paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mr. Berkowitz made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mr. Berkowitz made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support

this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p 183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mr. Berkowitz as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mr. Berkowitz was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal. Additionally, Mr. Berkowitz provided a Declaration stating that on the date of occurrence the child was recovering from eye surgery, that the child had a previous reaction to vaccination, and that the child's physician recommended delaying MMR vaccination.

Respondent-Appellant's Hearing Exhibit 79, Declaration of Ascher Berkowitz.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mr. Berkowitz reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

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**DOHMH v. Ascher Berkowitz
30376-19L0**

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30376-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

III. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a

fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

V. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VI. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation for a specified violation, as defined by paragraph (b) of subdivision 4 of this section, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>ASCHER BERKOWITZ 95 SKILLMAN STREET, #4C BROOKLYN, NY 11205</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30376-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30376-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30376-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 27, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019 the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and /or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

Appeal No. 30376-19L0

DOHMH v. J. Doe

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Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent submitted a declaration from the child's mother that on June 4, 2019, the child was healing from an eye surgery, that the child had had a previous reaction to a vaccine, and that on the pediatrician's advice she decided to delay MMR vaccination until the child's eye was fully healed.⁶ The mother's declaration was admitted into evidence without objection. Respondent suggested that no doctor's note was provided because the pediatrician feared the consequences of writing anything that said the child should not get a vaccine.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of an emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order that was claimed on scientific, religious, and moral grounds.⁸ As to the mother's declaration, Petitioner argued that although the child may or may not have been recovering from eye surgery that prevented vaccination on June 4 or while the child healed, there was ample time for compliance prior to that date. Petitioner also noted that by State law pediatricians are required to give notes for medical exemptions for other purposes, such as for school exams,⁹ and advised the hearing officer that Petitioner recently withdrew a similar case after verifying that a physician had indicated that the child might have had an exemption.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ Petitioner cited 10 NYCRR § 66-1.3, which sets forth required immunizations for school admission.

Appeal No. 30376-19L0

DOHMH v. J. Doe

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In the decision, the hearing officer credited the allegations contained in the summons. He found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that those arguments were beyond the scope of the hearing. On the merits of the case, the hearing officer found that "Respondent did not meet its burden in showing a medical exemption because a doctor's note was not provided by Respondent" and he sustained the violation.

On appeal, Respondent repeats by incorporation, the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹⁰ In addition, Respondent argues that he did not have a full and fair hearing because he could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds.

Petitioner asserts that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the named ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3), found in 48 RCNY of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

¹⁰ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

Appeal No. 30376-19L0

DOHMH v. J. Doe

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HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board’s authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner’s declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner’s suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

Appeal No. 30376-19L0

DOHMH v. J. Doe

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ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), the Commissioner of Health declared a public health emergency because of an outbreak of measles in certain ZIP codes in Brooklyn and issued an Order that required parents or guardians of children older than six months to have their children vaccinated against measles within forty-eight hours of the Order being signed unless they could demonstrate that the children had immunity to the disease or should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. As the summons in this case was dated after April 17, 2019, Respondent argues that it must be dismissed because by that date the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child had not been vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹¹

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹² There is no evidence in this record to show that Respondent offered any proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹³ As Respondent did not offer proof to contest any of the

¹¹ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹² *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018). After admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement.)

¹³ *See also Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

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essential facts establishing the violation, and the DOHMH physician, who had personal knowledge of the same vaccination records examined by the IO, was available to testify, there was no showing that the IO was needed. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

SUMMONS NUMBER: 30412-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: ISRAEL FISHMAN ID NUMBER: 50094215

ADDRESS: 140 Hewes St BROOKLYN, NY 11211 PHONE:

DATE AND TIME OF OCCURRENCE: June 12, 2019 AT 9:28 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 140 Hewes St BROOKLYN, NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 31, 2019 AT 10:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan
66 John Street
10th & 11th Floor
New York, NY 10038
- Staten Island
350 St. Marks Place
Main Floor
Staten Island, NY 10301
- Bronx
3030 Third Avenue
Room 250
Bronx, NY 10455
- Queens
31-00 47th Avenue
3rd & 4th Floor
Long Island City, NY 11435
- Brooklyn
9 Bond Street
6th & 7th Floor
Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

#	Code Section	Violation Description
1	NYC HC 3.05	In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, A.F., who is at least six months old, lives at: 140 Hewes St BROOKLYN, NY 11211, which is located in one of the affected zip codes listed in the Order. On June 12, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child A.F. has no record of measles immunization. Respondent has failed to vaccinate child A.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 2408 and 2409-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice.

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Pooja Jani Signature ID 06/13/2019 Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons. Received by:

Print Name Signature Title Date

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,

Petitioner,

Summons No.
30412-19L0

- against -

ISRAEL FISHMAN,

Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.

LORAIN PEONE, ESQ.

JENNIFER ROSEN, MD

PETITIONER'S REPRESENTATIVES

Department Of Health & Mental Hygiene

AARON SIRI, ESQ.

RESPONDENT'S REPRESENTATIVE

I N D E X

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>
<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
21.	Affidavit of Service		6
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
80.	Affidavit of Service affidavit		8
81.	Declaration		9
82.	Religious exemption		12

PROCEEDINGS

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1 H.O. DAVID LEUNG: Today's date is
2 September 25, 2019. It's 10:44 in the morning. My
3 name is David Leung, Hearing Officer. We are at the
4 Brooklyn OATH location on Department of Health issued
5 summons number 30412-19L0 issued to Israel Fishman.
6 It's an MMR related summons. We have attorney for
7 Department of Health here. Can you state your name
8 for the record?

9 MR. THOMAS¹ MERRILL: Thomas Merrill.

10 MS. LORAIN PEONE: Loraine Peone.

11 H.O. LEUNG: We also have a physician from
12 the Department of Health?

13 DR. JENNIFER ROSEN: Jennifer Rosen.

14 H.O. LEUNG: Dr. Rosen, do you swear or
15 affirm the testimony you give will be the truth?

16 DR. ROSEN: Yes.

17 [WHEREUPON THE WITNESS, J E N N I F E R R
18 O S E N, WAS DULY SWORN.]

19 H.O. LEUNG: Thank you. And we have an
20 attorney for the respondent?

21 MR. AARON SIRI: Aaron Siri.

22 H.O. LEUNG: Mr. Siri, do you waive the
23 need to have an interpreter? Do you understand the
24 penalty for the cited section of law is \$1,000? Do
25 you waive a formal reading of the charges and do you

PROCEEDINGS

5

1 understand both sides have a right to appeal?

2 MR. SIRI: I do.

3 H.O. LEUNG: Do you incorporate the
4 arguments that you made in previous hearing 30198-
5 19L0 as it pertains to your request to have the
6 issuing officer appear and also your constitutional
7 and non-constitutional arguments and all the evidence
8 that you submitted?

9 MR. SIRI: I do.

10 H.O. LEUNG: Any objection from Department
11 of Health?

12 MR. MERRILL: No, Your Honor.

13 H.O. LEUNG: Okay.

14 MR. MERRILL: With the understanding that
15 all exhibits come in.

16 H.O. LEUNG: Yes.

17 MR. MERRILL: Okay.

18 H.O. LEUNG: Department of Health, I'm
19 going to turn to you now since he has waived a
20 reading of the charges.

21 MR. MERRILL: Your Honor, we pretty much
22 rest on the NOV. The, the order and the resolution
23 were -- are, are in the record from the last
24 consolidate record. I'll just point out that this is
25 a five year old child living in Brooklyn who was not

PROCEEDINGS

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1 vaccinated as of when we checked the registry for his
2 status -- his or her status on June 12, 2019.

3 H.O. LEUNG: Mr. Siri?

4 MR. SIRI: I have got three additional
5 defenses. The first one is with regards to service.
6 My client alleges that they never received a copy of
7 the summons in the mail. I understand that the
8 Department of Health has an Affidavit of Service that
9 indicates it was mailed but my client attests here
10 that it was never received.

11 MR. MERRILL: I, I, I would -- again I've
12 given you a copy but here --

13 MR. SIRI: Yeah.

14 MR. MERRILL: -- here is a copy of the
15 Affidavit of Service for the record, Your Honor.

16 H.O. LEUNG: Okay. I'm going to mark this
17 as Petitioner's 21. Mr. Siri, any objection to the
18 Affidavit of Service coming in?

19 MR. SIRI: I don't have an objection. I'd
20 just like a quick look at it. No, no objection.

21 H.O. LEUNG: And Petitioner's 21 is
22 admitted. Is the Affidavit of Service -- the address
23 listed in the Affidavit of Service in P21 your
24 client's address to the best of your knowledge?

25 **[Petitioner's Exhibit 21 admitted into**

PROCEEDINGS

7

1 evidence.]

2 MR. SIRI: It's what the, it's what the
3 respondent declare as his address in the declaration
4 that we just submitted.

5 H.O. LEUNG: Okay. And are you submitting
6 anything in terms of evidence, an affidavit?

7 MR. SIRI: Yeah. So -- sorry. So, I've
8 got a declaration.

9 H.O. LEUNG: Okay.

10 MR. SIRI: This has the --

11 H.O. LEUNG: Okay. But real quick, I'm
12 sorry.

13 MR. SIRI: This has three separate
14 declarations in it, one for each of the three
15 defenses that we're going to raise. I'm just handing
16 them to you all at once.

17 H.O. LEUNG: Respondent's 80, I'm going to
18 mark first.

19 MR. SIRI: Yeah.

20 H.O. LEUNG: That's the Affidavit of
21 Service affidavit. Any objection to Respondent's 80
22 coming in?

23 MR. MERRILL: No, Your Honor.

24 H.O. LEUNG: Okay. Respondent's 80 is
25 admitted. And what other documents do you have?

PROCEEDINGS

8

1 [Respondent's Exhibit 80 admitted into
2 evidence.]

3 MR. SIRI: So, respond -- the second one is
4 a declaration which I believe would be Respondent's
5 81. And that is that the child at issue previously -
6 - older sibling had previously suffered from an
7 adverse reaction to the MMR vaccine. That adverse
8 reaction included among other things, loss of hearing
9 and delayed speech. And that -- and on that basis,
10 the mother did not want to give the child -- this
11 child MMR vaccine.

12 H.O. LEUNG: Okay. I've entertained
13 arguments regarding adverse reactions when it
14 pertains to a child under the age of 12 months old
15 because the argument there, it, it was that the, the
16 parent chose to delay providing the MMR vaccine
17 because the child was either too infirmed or had
18 health conditions under the age of 12 months old.
19 However, is your argument here that the parent
20 refused outright to provide --

21 MR. SIRI: Yes.

22 H.O. LEUNG: -- the MMR vaccine to this
23 five year old child?

24 MR. SIRI: That's right, because the
25 child's older sibling previously suffered from

PROCEEDINGS

9

1 hearing loss and speech delays from the MMR vaccine.

2 H.O. LEUNG: Okay. The first thing I'm
3 going to do is mark the second affidavit as
4 Respondent's 81 and I ask the Department of Health,
5 if they have any objection to Respondent's 81 coming
6 in?

7 MR. MERRILL: I, I don't have any objection
8 to it coming in, Your Honor.

9 H.O. LEUNG: Okay. Respondent's 81 is
10 admitted. How do you respond to this argument
11 regarding the five year old child?

12 **[Respondent's Exhibit 81 admitted into**
13 **evidence.]**

14 MR. MERRILL: So, again, I get -- I think
15 this gets to why the, why the, the State has said
16 that you need to have a document on the medical
17 exemption. Just, I don't dispute that this parent
18 may have had another child who got vaccinated, I
19 don't dispute that this child has -- may have issues
20 but I do think they are re-, you know, and I --
21 whether she has a belief that those issues may be
22 related but that doesn't mean that they were and that
23 doesn't mean that it is a medical exemption.

24 DR. ROSEN: Yeah. I, I will say from a
25 medical standpoint. Any reaction in household

PROCEEDINGS

10

1 members, family members is not at all a
2 contraindication to, to a child getting vaccinated.
3 The Advisory Committee on Immunization Practices sets
4 the national standard for recommendations for
5 immunizations including contradictions and reactions
6 or supposed reactions to vaccine in the family member
7 has no bearing and is not a contraindication to the,
8 to the actual child receiving the vaccination. And
9 then, again to Thomas' points, if a physician felt
10 that this child had a true contraindication for some
11 other reason of which this is not, but if the
12 physician thought there was a true contraindication,
13 then the parent would have needed to submit
14 documentation for a medical exemption.

15 MR. SIRI: When you say true
16 contraindication, you mean a contraindication listed
17 by the CDC, right?

18 DR. ROSEN: Contraindication based on
19 national standards --

20 MR. SIRI: Is --

21 DR. ROSEN: -- from the Advisory Committee
22 on Immunization Practices.

23 MR. SIRI: -- immunization practices which
24 is part of the CDC, correct?

25 DR. ROSEN: And no -- correct. There are -

PROCEEDINGS

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-

2

MR. SIRI: When you, when you say true

3

contraindication, I just want to make sure I

4

understand, you mean a contraindication listed on the

5

Advisory Committee on Immunization Practices lists of

6

contraindications for the MMR vaccine, correct?

7

DR. ROSEN: I'm talking about the

8

contraindications listed by the Advisory Committee on

9

the Immunization Practices which is the national

10

standard.

11

MR. SIRI: Okay. And then can you name one

12

study --

13

H.O. LEUNG: Mr. Siri?

14

MR. SIRI: One -- one question and I'm

15

done.

16

H.O. LEUNG: Go ahead.

17

MR. SIRI: Can you name me one study that

18

looked at whether or not an older sibling having a

19

reaction to MMR vaccine increase the risk that a

20

younger sibling would have a reaction to MMR vaccine?

21

DR. ROSEN: The Advisory Committee on

22

Immunization Practices clearly states what the

23

contraindications are and what's accepted as the

24

standards.

25

MR. SIRI: So, the answer is no. I

PROCEEDINGS

12

1 understand.

2 H.O. LEUNG: And Mr. Siri, just so I'm
3 clear, the two documents that you submitted --

4 MR. MERRILL: There is three actually --

5 H.O. LEUNG: Three, I'm sorry, three? Let
6 me just make sure I have them and marked.

7 MR. MERRILL: Yeah, there is a third --
8 there was third page up there.

9 H.O. LEUNG: There is a third -- okay, I
10 only have two marked as Respondent's 81 and 82 I
11 believe, 80 and 81.

12 MR. MERRILL: There is a religious
13 exemption declaration.

14 MR. SIRI: Yeah. Yeah, and there's --

15 H.O. LEUNG: And so, Respondent's 83 is a
16 religious exemption?

17 MR. SIRI: Yes. And this is the client's
18 religious statement that we're submitting.

19 H.O. LEUNG: Okay. Okay. So, Respondent's
20 82 is the religious exemption. And just so I'm
21 clear, Mr. Siri, you do not have a physician's note
22 regarding the child, is that correct? It's, it's the
23 affidavit from the mother?

24 **[Respondent's Exhibit 82 admitted into**
25 **evidence.]**

PROCEEDINGS

13

1 MR. SIRI: The declaration of the mother,
2 that's right.

3 MS. PEONE: Father, it was the father.

4 MR. SIRI: Oh, the father, I'm sorry.

5 H.O. LEUNG: I apologize, from the father.

6 MR. SIRI: It's the father, yeah.

7 [OFF MIC CONVERSATION]

8 H.O. LEUNG: As to this summons, I have
9 enough to make a decision. Both sides will receive
10 my written decision within 30 days. Hearing nothing
11 further, this hearing is closed. Thank you.

12 [END OF HEARING]

13

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health & Hygiene v. Israel Fishman on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>ISRAEL FISHMAN 140 HEWES STREET BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30412-19L0</u></p> <p>Decision Date: <u>9/25/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
--	--

Summary Disposition: Sustained

LINE ITEM	VIOL CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on June 12, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

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			<p>in Williamsburg, Brooklyn, which included zip code 11211 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of June 12, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
--	--	--	---	--	--

Dell...

				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>Respondent provided an affidavit stating that although a copy of the summons was taped to Respondent's apartment door, she never received a copy in the mail. (R80) In response, Petitioner provided a copy of the Certificate of Service and mailing (P21) I credit Petitioner's Certificate of Service and find that a copy of the summons was properly mailed to Respondent's address.</p> <p>Respondent provided an affidavit stating that the child's older sibling suffered an adverse reaction to the MMR vaccine. Dr. Rosen responded by stating that the fact that the child's older sibling suffered an adverse reaction to the MMR vaccine is not a medical justification to avoid administering the MMR vaccine to the child in question. I credit Dr. Rosen's testimony and find that respondent did not establish a medical exemption for the child.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

Dell'Isola

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division **within 30 days** of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received **within 30 days** of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
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or call 1-844-OATH-NYC

GN3c Decision Back Health 5-9-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Israel Fishman

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30412-19L0

NOTICE OF APPEAL

Respondent Israel Fishman ("Mr. Fishman") hereby appeals the decision on Summons Number 30412-19L0 (the "Summons").¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the "Commissioner") issued an Order (the "Commissioner's Order") requiring that certain categories of people in certain zip codes be injected with Merck's product M-M-R-II, also known as the measles, mumps, rubella ("MMR"), within forty-eight hours of the Commissioner's Order. **Petitioner-Appellee's Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the "Board") created a resolution (the "Resolution") which also required administration of the MMR vaccine, but defined what constituted a "nuisance" completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mr. Fishman submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On June 13, 2019, Mr. Fishman was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for his child A.F. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summon should have been dismissed and that the Hearing Officer deprived Mr. Fishman of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On June 13, 2019 Mr. Fishman was cited as having violated the Commissioner's Order by failing to vaccinate his child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mr. Fishman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on June 13, 2019, alleges a violation that occurred on June 12, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mr. Fishman alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mr. Fishman violated the Commissioner’s Order on June 12, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[]" or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was June 12, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE MR. FISHMAN WAS NOT PROVIDED PROPER SERVICE OF THE SUMMONS

Another independent basis for dismissing the Summons exists because Mr. Fishman was not provided proper service of the Summons. The Summons was attached to Mr. Fishman's apartment door; however, he did not receive a copy of the Summons via United States Postal Service. **Respondent-Appellant's Hearing Exhibit 81, Declaration of Israel Fishman, Improper Service.** Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Mr. Fishman was not provided proper legal service, and the Tribunal must

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MR. FISHMAN AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mr. Fishman. Due process requires that Mr. Fishman be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mr. Fishman be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school,

Petitioner-Appellee's Hearing Exhibit 2. Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mr. Fishman from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles." **Exhibit A, Summons**. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons**. (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mr. Fishman must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mr. Fishman is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mr. Fishman of mounting a viable

preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2**. (emphasis added.) The distinction between the words "live" and "reside" are legally significant. *See, argument at Section I, p 5.*

defense to the Summons. Furthermore, Mr. Fishman was clearly not provided “an accurate statement of the matter to be adjudicated” as required by NYCC § 1046.

In sum, the Commissioner’s Order and the Board’s Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mr. Fishman an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. FISHMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Fishman of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mr. Fishman proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mr. Fishman’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“Dr. Rosen”), was available and could answer any questions

regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child's address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mr. Fishman to determine if the child had been given MMR before the Summons was issued (**Hearing Transcript, p 117-118**).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mr. Fishman the ability to cross-examine the issuing officer and deprive Mr. Fishman of a full and fair hearing, and the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. FISHMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Fishman of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mr. Fishman's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mr. Fishman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mr. Fishman's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mr. Fishman of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mr. Fishman "*relied upon* the last paragraph of the Order, which states, '[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board'" to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mr. Fishman did not *rely upon* this statement made in the Commissioner's Order. Instead, Mr. Fishman's argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner's Order. In fact, counsel for Mr. Fishman read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mr. Fishman paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mr. Fishman made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion,

and cited to and read into the record the Hearing Officer's authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mr. Fishman made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states "medically appropriate" as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the "April 17, 2019 Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order." **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner's Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner's Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer's finding that the Commissioner's "exercise of authority" was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mr. Fishman as having violated the Commissioner's written order, not the Commissioner's exercise of emergency authority. Therefore, the Hearing Officer's finding that the Board continued the Commissioner's exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer's decision lacked a rational basis and is not factually supported; hence, Mr. Fishman was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine ("IOM"), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 – Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants

who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 - NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 - Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 - NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 - Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 - Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 - American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 - Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 - PLoS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal. Additionally, Mr. Fishman's older child suffered an adverse reaction to the MMR vaccine that resulted in a loss of hearing and delayed speech, among other things. **Respondent-Appellant's Hearing Exhibit 82, Declaration of Israel Fishman, Adverse Reaction.**

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VIII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mr. Fishman reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

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Attorneys for Respondent-Appellant

DOHMH v. Israel Fishman
30412-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30412-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. Respondent was properly served the Summons

The hearing officer was correct in concluding that Respondent was provided proper service as was evidenced in the submitted certificate of service that stated the Summons was mailed. Improper mailing is not proven simply by a declaration of Respondent that she did not receive the mailing. *See DOHMH v. Joan Moriello*, Appeal No. 1801264 (December 12, 2018) ("Her mere denial that she received the mailing is inadequate to overcome the presumption that properly addressed mail is received, absent any evidence or testimony demonstrating the mailing would be unlikely to arrive.") (*citing DOB v. Banyer Place Development LLC*, Appeal No. 1800075 (April 5, 2018)).

Accordingly, the decision should be affirmed.

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical

appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) (“Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.”).

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, “Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector’s testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the

Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5)(“...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VIII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s*

Cycles, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>ISRAEL FISHMAN 140 HEWES STREET BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30412-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: AFFA

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3:05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
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Appeal No. 30412-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30412-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed on June 13, 2019, that on June 12, 2019, she reviewed the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), and observed that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and /or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. Petitioner added that the subject child in this case was five years old. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and that Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent added three additional defenses: (1) that the parent asserted he never received the summons in the mail; however, Respondent acknowledged Petitioner's affidavit of service, which was taken into evidence without objection; (2) that the parent did not have the child vaccinated because an older sibling had had an adverse reaction to the MMR vaccination, including loss of hearing and delayed speech, as established by the parent's declaration taken into evidence without objection; and (3) that there was an objection on religious grounds.⁶

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Commissioner's Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself was an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ As to the new defenses raised in this hearing, Petitioner asserted that a parent's belief that a child's issues were related to a vaccination did not mean that they were, nor did it establish a medical exemption. Citing the national standard for recommendations for immunizations set by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC), the DOHMH physician testified that any reaction in a household member or family member was not a contra-indication and that the parent would have needed to submit documentation for a medical exemption.

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician indicated that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live in the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ "MMR" stands for Measles, Mumps, Rubella.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue an earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

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In the decision, the hearing officer sustained the violation, finding that the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to HC § 3.01; that the Commissioner by her Order, and the Board by its Resolution, directed that persons six months of age or older who live, work or reside in the specified ZIP codes be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception. The hearing officer rejected Respondent's argument that the Order had expired when the summons was written, finding that the BOH, by its Resolution of April 17, 2019, had continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Order. The hearing officer found that Respondent's Constitutional and scientific arguments were beyond the scope of the hearing. He credited Petitioner's affidavit of service and found that the summons was properly mailed to Respondent's address. He found that Respondent's evidence had not established a medical exemption for the child, and that Respondent had failed to provide a defense to the allegations.

On appeal, Respondent repeats the arguments raised in the hearing relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles, and the specific argument in this case that service of the summons was not proper.⁹ In addition, Respondent argues that he did not have a full and fair hearing because he could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Finally, Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to § 1049 of the NYCC, found in Chapter 45-A; and on NYS and United States Constitutional grounds.

In response, Petitioner argues that the hearing officer's finding was correct that the Order of April 9, 2019, was continued by the BOH Resolution dated April 17, 2019, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the Board to continue the Order as is, but that the Board's powers are not limited to continuing or rescinding the Order. Petitioner argues that the Resolution continued the Commissioner's exercise of power asserted in the Order since the Resolution repeats the main directive of the Order, which is that people living in the named ZIP codes shall be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that even if it is found that the Resolution was not in effect until completion of publication, the Resolution "is a continuation of the Commissioner's Order and therefore on the date of the occurrence alleged, April 21, 2019, Respondent was in violation of both the Order and the Resolution continuing the Order." Petitioner argues that the summons provided adequate notice of the charges pursuant to § 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

⁹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power. . . .

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent

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or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within 48 hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was signed on April 9, 2019, and was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order had expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 12, 2019. That examination provided uncontroverted evidence that the child had never been vaccinated, a fact that was admitted, and therefore was not vaccinated during the forty-eight hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by the expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in this record to show that Respondent offered proof of immunity or documentation,

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ *See DCA V. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

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such as a doctor's note, that that vaccination was medically inappropriate specifically for this child. It was not error for the hearing officer to credit the DOHMH physician's position that an adverse reaction by a sibling did not establish a medical exemption for the subject child. In addition, the Tribunal finds that the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing was reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹²See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994). (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and where there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30378-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE
DIVISION: Disease Control BUREAU: Immunization
AGENCY ADDRESS AND PHONE NUMBER: 42-09 29th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: MALKA FRIEDMAN ID NUMBER: 50093819
ADDRESS: 564 WYTHE AVE #8A BROOKLYN NY 11249 PHONE:
DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:36 AM BOROUGH: Brooklyn
PLACE OF OCCURRENCE: 564 WYTHE AVE #8A BROOKLYN NY 11249

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 24, 2019 AT 9:00 AM
** RESPONDENT MUST APPEAR IN PERSON **
OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan 66 John Street 10th & 11th Floor New York, NY 10038
Staten Island 350 St. Marks Place Main Floor Staten Island, NY 10301
Bronx 3030 Third Avenue Room 250 Bronx, NY 10455
Queens 31-00 47th Avenue 3rd & 4th Floor Long Island City, NY 11435
XX Brooklyn 9 Bond Street 6th & 7th Floor Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.
REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Table with 2 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order.

NYC Charter Sections 2048 and 2049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice.

I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Poolia Jani Signature ID Date 06/04/2019
Print Name Signature Title Date

I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.

Print Name Signature Title Date

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you MUST APPEAR IN PERSON, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,
 Petitioner,

Summons No.
30378-19L0

- against -

MALKA FRIEDMAN,

Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.

LORAIN PEONE, ESQ.

JENNIFER ROSEN, MD

PETITIONER'S REPRESENTATIVES

Department Of Health & Mental Hygiene

AARON SIRI, ESQ.

RESPONDENT'S REPRESENTATIVE

I N D E X

3

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>
<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
84.	Declaration from Ms. Friedman		6
85.	Religious belief from Ms. Friedman		6

PROCEEDINGS

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1 H.O. DAVID LEUNG: Okay. It's September
2 25, 2019. It's 10:53 in the morning. My name is
3 David Leung, Hearing Officer. We are here today on
4 the Department of Health issued summons 30378-19L0
5 issued to Malka Friedman. It's an MMR related
6 summons. We have attorneys from the DOH here.

7 MR. THOMAS MERRILL: Thomas Merrill.

8 MS. LORAIN PEONE: Loraine Peone.

9 H.O. LEUNG: And we also have a physician
10 from the Department of Health?

11 DR. JENNIFER ROSEN: Jennifer Rosen.

12 H.O. LEUNG: Dr. Rosen, do you swear or
13 affirm the testimony you give will be the truth?

14 MS. ROSEN: Yes.

15 [WHEREUPON THE WITNESS, J E N N I F E R R
16 O S E N, WAS DULY SWORN.]

17 H.O. LEUNG: We also have an attorney for
18 respondent here?

19 MR. AARON SIRI: Aaron Siri.

20 H.O. LEUNG: Mr. Siri, do you waive
21 interpreter services? Do you waive a formal reading
22 of the summons? Do you understand both sides have
23 the right to appeal and that the penalty for the
24 cited violation is \$1,000?

25 MR. SIRI: I do.

PROCEEDINGS

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1 H.O. LEUNG: Do you incorporate the
2 arguments, evidence that you made in summons number
3 30198-19L0 which is a three hour hearing that we held
4 on the previous date?

5 MR. SIRI: I do, as well as all the
6 exhibits therein.

7 H.O. LEUNG: Great. Any objection,
8 Department of Health?

9 MR. MERRILL: No, Your Honor, with the
10 understanding that all exhibits from both sides are
11 coming in.

12 H.O. LEUNG: Okay. And part of that
13 argument in that previous hearing was that you
14 requested the appearance of the issuing officer and I
15 made a ruling on that in the previous hearing. Is
16 that correct? Mr. Siri?

17 MR. SIRI: Yes.

18 H.O. LEUNG: Okay. Since Mr. Siri has
19 waived the formal reading of the summons, I'm going
20 to turn immediately to the Department of Health.

21 MR. MERRILL: Your Honor, again, the order
22 of the Commissioner and the Board resolution had
23 previously been put into evidence in consolidate
24 record. This is a case where we checked the registry
25 on June 4th and the child, who is four years old --

PROCEEDINGS

6

1 five, five years old had not yet been vaccinated.

2 H.O. LEUNG: Mr. Siri?

3 MR. SIRI: Okay. I have got two additional
4 defenses. The first one is that it's a declaration
5 from the respondent that on the date the NOV was
6 issued, June 4th, the child had a moderate acute
7 illness. And then the second defense, an additional
8 defense is that they have a religious basis for not
9 vaccinating. I provide those declarations to the --

10 H.O. LEUNG: Okay. The declaration from
11 Ms. Friedman is going to be marked as Respondent's 83
12 and the --

13 MS. PEONE: I think we are on 84.

14 H.O. LEUNG: Are we? Let me just double
15 check that. Okay, 84, excuse me. And the religious
16 belief affidavit from Ms. Friedman will be
17 Respondent's 85. Department of Health, any objection
18 to 84 and 85 coming in?

19 MR. MERRILL: No, Your Honor.

20 H.O. LEUNG: Thus, both admitted without
21 objection. Department of Health, how do you respond
22 to these affidavits?

23 **[Respondent's Exhibits 84 and 85 admitted**
24 **into evidence.]**

25 MR. MERRILL: The religious one, Your

PROCEEDINGS

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1 Honor, that's -- that's come up in other cases. It's
2 simply not a defense. So, despite what her beliefs
3 may be, it's not a defense to the order. Regarding
4 the, the declaration on the, on the mother of acute
5 illness, I -- there is -- regarding on the cases,
6 there is no, there is no doctor's affidavit here. I
7 would argue it would be required, but more
8 importantly again, whether or not the child was
9 moderately ill on June 4th, so as the child could not
10 be vac-, could not receive the actual vaccine on that
11 date. The fact of the matter is that the kid was
12 still violating the order and that they are not being
13 vaccinated and they had a ample opportunity to comply
14 with the order and resolution prior to that.

15 H.O. LEUNG: Anything you want to respond
16 to that, Mr. Siri?

17 MR. SIRI: No, Your Honor.

18 H.O. LEUNG: Okay. Having heard both
19 sides, I have enough to make a decision. I'm going
20 to issue a written decision within 30 days. Hearing
21 nothing further, this hearing is closed. Thank you.

22 [END OF HEARING]
23

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health & Hygiene v. Malka Friedman on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC
256 West 38th Street - 10th Floor
New York, NY 10018


OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
 Hearings Division

 9 Bond Street, 7th Floor
 Brooklyn, NY 11201

DECISION

DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against- MALKA FRIEDMAN 564 WYTHE AVENUE, #8A BROOKLYN, NY 11249 (Respondent)	Violation/Summons No.: <u>30378-19L0</u> Decision Date: <u>9/25/2019</u> Hearing Officer: <u>Leung David</u> Respondent's Rep.: <u>Aaron Siri, Esq.</u> Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u> Type of Hearing: <u>In Person</u>
---	---

 Summary Disposition: Sustained

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on June 4, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

				<p>in Williamsburg, Brooklyn, which included zip code 11249 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of June 4, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
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				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent provided an affidavit stating that the child had a "moderate acute illness" on the date of issuance. (R84) Petitioner argued that Respondent did not meet its burden in showing a medical exemption because a doctor's note was not provided by Respondent. On this record, I find that Respondent failed to adequately show/prove a medical exemption. I based this finding on the fact that a doctor's note was not provided to support the vague description of the child's condition- "Moderate acute illness."</p> <p>Respondent also submitted an affidavit attesting to Respondent's religious objection to the MMR vaccine. (R85). Petitioner replied that a religious objection is not a valid defense to the allegations. I credit Petitioner's testimony and argument pertaining to the issue.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					<p>TOTAL:</p>	<p>\$1,000.00</p>

D. J. [Signature]

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Malka Friedman

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30378-19L0

NOTICE OF APPEAL

Respondent Malka Friedman (“**Mrs. Friedman**”) hereby appeals the decision on Summons Number 30378-19L0 (the “**Summons**”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “**Commissioner**”) issued an Order (the “**Commissioner’s Order**”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“**MMR**”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “**Board**”) created a resolution (the “**Resolution**”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mrs. Friedman submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On June 4, 2019, Mrs. Friedman was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child Y.F. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summon should have been dismissed and that the Hearing Officer deprived Mrs. Friedman of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On June 4, 2019, Mrs. Friedman was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "**Hearing Officer**") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Friedman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on June 4, 2019, alleges a violation that occurred on June 4, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Friedman alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Friedman violated the Commissioner’s Order on June 4, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p 58.** The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was June 4, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. FRIEDMAN AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Friedman. Due process requires that Mrs. Friedman be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached)

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Friedman be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Friedman from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside**, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. *See*, argument at Section I, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Friedman must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Friedman is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Friedman of mounting a viable defense to the Summons. Furthermore, Mrs. Friedman was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Friedman an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FRIEDMAN OF A FULL AND FAIR HEARING BY

**REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER
WHERE A DISPUTE OF FACT WAS PRESENTED**

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Friedman of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Friedman proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Friedman’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“**Dr. Rosen**”), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child’s address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Friedman to determine if the child had been given MMR before the Summons

was issued (**Hearing Transcript, p 117-118**).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Friedman the ability to cross-examine the issuing officer and deprive Mrs. Friedman of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FRIEDMAN OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Friedman of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Friedman's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Friedman's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Friedman of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Friedman's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Friedman “*relied upon* the last paragraph of the Order, which states, ‘[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board’” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Friedman did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mrs. Friedman’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mrs. Friedman read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Friedman paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Friedman made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Friedman made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support

this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Friedman as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mrs. Friedman was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* (“M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility”).

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal. Additionally, Mr. Friedman submitted a declaration stating that the child had “a moderate acute illness” on the date of occurrence listed on the Summons. **Respondent-Appellant’s Hearing Exhibit 84, Declaration of Shea Friedman, MMR not Medically Appropriate.** According to CDC guidance, vaccination with MMR should be deferred for persons with “moderate acute illness.” See, *Vaccine Recommendations and Guidelines of the ACIP*, page 50, available at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD’S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner’s Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Friedman reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and

⁹ “Respondent’s Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal.” *TLC. v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

Dated: November 30, 2019

SIRI & GLIMSTAD LLP



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Attorneys for Respondent-Appellant

DOHMH v. Malka Friedman
30378-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30378-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health herby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

III. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a

fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

V. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), *citing Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VI. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation for a specified violation, as defined by paragraph (b) of subdivision 4 of this section, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>MALKA FRIEDMAN 564 WYTHE AVENUE, #8A BROOKLYN, NY 11249</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30378-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: AFFA

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05		Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

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 New York, NY 10038
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Appeal No. 30378-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30378-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent submitted a declaration from the child's father that on June 4, 2019, the date the summons was issued, the child had a moderate, acute illness, and a second declaration that, based on witnessing "two vaccine injuries," he believed that the vaccination was against his religious belief because "[w]e are forbidden to take any drug or do anything that can cause us harm." The declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05 for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁷ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds. Petitioner argued that a religious objection was not a defense to the Order. Petitioner also noted that the subject child was five years old.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that those issues were beyond the scope of the hearing. The hearing officer found that without a doctor's note to support the "vague description" of the child's illness, Respondent had failed to prove a medical exemption on the date of issuance. In addition, he

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

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found that Respondent's declaration of religious objection was not a valid defense. He credited Petitioner's allegations and found that the Respondent's evidence did not provide a defense.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

⁹ "MMR" stands for Measles, Mumps, Rubella.

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and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or

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guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. Even if the child was ill on the day the summons was issued, the violation was established by the failure to vaccinate during the time specified in the Order. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

Appeal No. 30378-19L0

DOHMH v. J. Doe

p. 6 of 6

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

SUMMONS NUMBER: 30304-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Judith Fried ID NUMBER: 50092652
ADDRESS: 42 Walton Street APT# 3A, Brooklyn NY 11206 PHONE:
DATE AND TIME OF OCCURRENCE: May 10, 2019 AT 2:22 PM BOROUGH: Brooklyn
PLACE OF OCCURRENCE: 42 Walton Street APT# 3A, Brooklyn NY 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 3, 2019 AT 9:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan 66 John Street 10th & 11th Floor New York, NY 10038
Staten Island 350 St. Marks Place Main Floor Staten Island, NY 10301
Bronx 3030 Third Avenue Room 250 Bronx, NY 10455
Queens 31-00 47th Avenue 3rd & 4th Floor Long Island City, NY 11435
XX Brooklyn 9 Bond Street 5th & 7th Floor Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, H.F., who is at least six months old, lives at: 42 Walton Street APT# 3A, Brooklyn NY 11206, which is located in one of the affected zip codes listed in the Order. On May 10, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child H.F. has no record of measles immunization. Respondent has failed to vaccinate child H.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 204B and 2049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice. I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Jane Bedell Signature Date 5/13/2019
I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons.
Received by: Print Name Signature Title Date

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038
Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201
Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435
Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455
Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH AND MENTAL HYGIENE,

Petitioner,

Summons No.
30304-19L0

- against -

JUDITH FRIED,

Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
LORRAINE PEONNE, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVES
Department of Health And Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>
<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
23.	Affidavit of Service	5	6
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
91.	Guidance from nycourts.gov	7	7
92.	Affidavit	13	14
93.	Affidavit	13	14
94.	Affidavit	13	14
95.	Religious Statement	14	14

PROCEEDINGS

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1 H.O. DAVID LEUNG: Okay, great, we're on
2 the record. Today's date is September 25, 2019.
3 It's 11:09 in the morning. We're at the Brooklyn
4 OATH location. Health Department issued summons
5 30304-19L0 issued to Judith Fried. We have attorneys
6 for Department of Health here.

7 MR. THOMAS MERRILL: Sorry, Thomas Merrill.

8 MS. LORRAINE PEONNE: It's okay. Lorraine
9 Peonne.

10 H.O. LEUNG: And then we have a physician
11 from the Department of Health.

12 DR. JENNIFER ROSEN: Jennifer Rosen.

13 H.O. LEUNG: Dr. Rosen, do you swear to
14 tell the truth?

15 DR. ROSEN: Yes.

16 [WHEREUPON THE WITNESS, J E N N I F E R R
17 O S E N, WAS DULY SWORN.]

18 H.O. LEUNG: Thank you. Mr. Siri, you want
19 to put your name on the record for respondent.

20 MR. AARON SIRI: Aaron Siri.

21 H.O. LEUNG: Thank you. Do you waive
22 interpreter, the need to have -- sorry, I'm going to
23 go back to do you waive interpreter? Do you
24 understand the penalty carries -- the cited section
25 of law carries a \$1,000 penalty. You have a right to

PROCEEDINGS

5

1 appeal. And do you waive the formal reading of the
2 summons?

3 MR. SIRI: I do, Your Honor.

4 H.O. LEUNG: Do you incorporate the
5 arguments, evidence and testimony in 30198-19L0, a
6 previously, a previous hearing?

7 MR. SIRI: Yes, I do.

8 H.O. LEUNG: Alrighty. Department of
9 Health.

10 MR. MERRILL: Yes, Your Honor, the Board of
11 Health resolution and [unintelligible] [01:09] record
12 from our last date here. This is a case where we
13 checked the registry on May 10th and the child was in
14 Brooklyn, had come back to the States despite being
15 over six months old and living in Brooklyn.

16 H.O. LEUNG: Mr. Siri.

17 MR. SIRI: I'd like to ask for the
18 affidavit of service.

19 MR. MERRILL: I'll put that up now. I'll
20 just, I'll hand it to you and then you can reply when
21 you're done with it.

22 MR. SIRI: Sure.

23 MR. MERRILL: Service, claim submitted
24 pers-, on, on the person on May, May 14th.

25 H.O. LEUNG: I'm going to mark that as

PROCEEDINGS

6

1 Petitioner's 23.

2 [Petitioner's Exhibit 23 admitted into
3 evidence.]

4 MR. SIRI: So the affidavit of service as
5 the client recalls provides that it was served after
6 11:00 p.m. at night which is improper. We'd ask that
7 it be withdrawn or dismissed on that basis. It says
8 11:15 p.m.

9 H.O. LEUNG: Yeah, no, just -- you have
10 more experience. Is there a legal objection?

11 MR. SIRI: After 11:00 p.m.

12 H.O. LEUNG: [Unintelligible] [02:16].

13 MR. SIRI: Yeah, well, you know, there's --
14 I -- sure.

15 H.O. LEUNG: Okay.

16 MR. SIRI: This one's 10:00 p.m. at night.
17 There are other provisions that say 11:00.

18 H.O. LEUNG: Okay, no, I meant --

19 MR. SIRI: Yeah.

20 H.O. LEUNG: I haven't litigated in 20
21 years so...

22 MR. SIRI: Okay. You're welcome.

23 H.O. LEUNG: And what section of law are
24 you citing as the basis for -- you just provided
25 documents.

PROCEEDINGS

7

1 MR. SIRI: Yes.

2 H.O. LEUNG: The cited section of law?

3 MR. SIRI: Yeah, I mean, it's in the CPLR
4 as well. I just thought there was -- I, I just, I
5 just, you know, all the litigations I've done we know
6 not to serve and I never...

7 MR. MERRILL: It's a guidance document from
8 NYC Courts, Your Honor, so it doesn't have a cite
9 here.

10 MR. SIRI: Yeah.

11 MR. MERRILL: No, what I'm trying to
12 [unintelligible] [03:06]. Can I see the affidavit of
13 service again?

14 H.O. LEUNG: Yeah, sure.

15 MR. MERRILL: I did not look at the time.

16 H.O. LEUNG: I'm going to mark the, the
17 piece of paper here from the guidance, nycourts.gov,
18 a Respondent's 91. Any objection to me putting this
19 into evidence, counsel?

20 MR. MERRILL: No, Your Honor.

21 [Respondent's Exhibit 91 admitted into
22 evidence.]

23 MS. PEONNE: You said 91?

24 H.O. LEUNG: I just marked 91.

25 MS. PEONNE: Okay, thank you.

PROCEEDINGS

8

1 H.O. LEUNG: Yeah. The CPLR provision for
2 this.

3 MS. PEONNE: Okay.

4 MR. MERRILL: Can I have a look at -- I
5 think that is guidance for Housing Court, Your Honor,
6 not that it -- but, but, you know, I just, I'm just
7 reading something else it says. You know, in Housing
8 Court papers should be served 6:00 p.m. at night. I,
9 again, I don't, I'm not, you know, doing research
10 here on the fly. I can't find a rule per se that you
11 can't serve after 11:00 and given that the sheriff's,
12 I would assume the sheriff would comply with that
13 given that their duties are to serve.

14 H.O. LEUNG: And the only restrictions I
15 see under the general business laws is prohibition of
16 the service process on a Sunday and then
17 [unintelligible] [06:00] serving process on Saturday
18 when a person keeps Saturday as a holy time which is
19 a Sabbath. I understand the argument and I'll do, I
20 mean, I'm going to have to look this up and..

21 MR. SIRI: Yeah.

22 H.O. LEUNG: I don't know. But if you can
23 cite something that you know to help me that would
24 save me some time, but if you --

25 MR. SIRI: I could tell you

PROCEEDINGS

9

1 [unintelligible] [06:21] represent, I represent that
2 in, you know, over the course of many years in
3 litigation. I've always understood that to be the
4 rule, but admittedly I don't have -- or is it --
5 yeah.

6 MS. PEONNE: Your Honor, I actually have
7 another case so I'm going to step out.

8 H.O. LEUNG: No problem, okay.

9 MS. PEONNE: Thank you.

10 H.O. LEUNG: Yeah.

11 MR. MERRILL: I'm just telling you that
12 because I'm going to be much more awkward.

13 H.O. LEUNG: Okay, I understand your
14 argument.

15 MR. SIRI: Yeah.

16 H.O. LEUNG: You're alleging that --

17 MR. SIRI: I'm looking it up.

18 H.O. LEUNG: - the 11:15 service time on
19 Petitioner's 23 which is the affidavit of service
20 makes the summons, the service invalid. You're
21 relying on what you believe to be a section of law in
22 the general business law, though everyone here -- I
23 have looked for the last five minutes, counsel for
24 DOH has looked and you're looking and it's something
25 that I'm going to have to [unintelligible] [07:40] --

PROCEEDINGS

10

1 MR. SIRI: Yeah.

2 H.O. LEUNG: And resolve but --

3 MR. SIRI: You know, what I -- I've gone
4 through the -- but this is almost, I say this with a
5 little bit of embarrassment. I've gone to a few of
6 the, you know, service websites and they all say you
7 can't serve outside of 6:00 and, 6:00 a.m. and 10:00
8 p.m. I was always sure 11:00 p.m. They don't cite
9 for it and so --

10 H.O. LEUNG: But I, look, what I saw when I
11 did the research is that it's frowned upon.

12 MR. SIRI: I'm sure they get that from
13 something.

14 H.O. LEUNG: Right.

15 MR. SIRI: From someplace. I just thought
16 it would be something that would be accepted but fair
17 enough. If the court can indulge me just for one
18 more quick minute though.

19 H.O. LEUNG: Is the service your only
20 argument on this or do you have another argument?

21 MR. SIRI: I do have other arguments.
22 I was hoping this would dispose of it then. Okay.
23 So the general, general business law 7-11 outside of
24 6 and 10 under the general business law, it's frowned
25 upon, but if the court determines it's service made

PROCEEDINGS

11

1 at an off hour basically and purposefully --

2 H.O. LEUNG: Is it 7-11? Is that where
3 you're reading from? I just want to make sure.

4 MR. SIRI: Yeah.

5 H.O. LEUNG: Because I'm not, I'm not...

6 MR. SIRI: Yeah.

7 H.O. LEUNG: And you're saying that the
8 statute as you read it says it's frowned upon?

9 MR. SIRI: No, that's somebody else's
10 inter- [unintelligible] [09:26].

11 H.O. LEUNG: Okay.

12 MR. SIRI: I should give you an actual
13 cite. What's that?

14 MR. MERRILL: [Unintelligible] [09:32].

15 MR. SIRI: I mean, you know, usually the
16 tribunal knows the law so I'm going to leave it in
17 your hands, unfortunately.

18 H.O. LEUNG: Okay, I'll find out what it
19 is. But I understand your argument. We can move on
20 to your next argument.

21 MR. SIRI: Yeah. And so you can look for
22 that provision if you can find it. So the next
23 argument is that the child is under 12 months of age
24 and there's no license [unintelligible] [09:58]
25 vaccine for a child under 12 months of age. I'll

PROCEEDINGS

12

1 just give them all to you. Second is that the child,
2 the child's sibling previously suffered a moderate to
3 severe adverse vaccine reaction. The parent has a
4 religious objection to the vaccination.

5 H.O. LEUNG: Do you have an affidavit
6 individually for each of these?

7 MR. SIRI: For each of these, I do.

8 H.O. LEUNG: Okay. How old was the child
9 at the time of issuance?

10 MR. SIRI: Under 12 months of age.

11 H.O. LEUNG: Under 12 months. Doctor, I'm
12 going to let you respond to Respondent's 92 which is
13 the affidavit from the child's parent saying that
14 they --

15 MR. SIRI: Here's the affidavit.

16 H.O. LEUNG: Some MMR vaccine is not
17 licensed for a child under 12 months of age and also
18 Respondent's 93 which is the child's sibling suffered
19 from moderate reaction to the MMR vaccine and the
20 parent chose to -- did she choose to delay or choose
21 -- what's the wording on -- let me just get that, to
22 not give the vaccination to this child.

23 DR. ROSEN: I'll first address the issue of
24 vaccinating under the age of one. The Advisory
25 Committee on Immunization Practices which sets the

PROCEEDINGS

13

1 national standard for vaccination has recommendations
2 for all infants aged six to 11 months to get MMR
3 vaccine prior to international travel, and they state
4 that during an outbreak MMR vaccine may be used for
5 infants aged six to 11 months. With regard to the
6 siblings that the Advisory Committee on Immunization
7 Practices sets the national standards for what's
8 considered contraindications and precautions to
9 vaccinations of which reactions in siblings is not
10 one, so there is, so reactions in siblings is not a
11 contraindication or a precaution to this child
12 receiving vaccinations. And further, if there were
13 some contraindication that were valid of which this
14 is not, if ever, then the physician, then the parent
15 would have been free to submit a document citing a
16 medical exemption from a physician which we don't
17 have.

18 H.O. LEUNG: Okay. Mr. Siri, I've marked
19 as Respondent's 92 the child's, the affidavit
20 regarding the child's sibling suffering the reaction.
21 I've marked as Respondent's 93 the child, the
22 affidavit stating that the child is under 12 months
23 of age. I've marked as Respondent's 94 the affidavit
24 of delivery, the affidavit from the parent saying
25 that the delivery of the summons occurred after 11:00

PROCEEDINGS

14

1 p.m. And then I have some handwritten notes. What
2 are these?

3 MR. SIRI: That is the, I believe that is,
4 that's the religious statement, Your Honor.

5 H.O. LEUNG: Okay, so that's Respondent's
6 95 is religious statement. I'm going to show this to
7 Mr. Merrill and ask in terms of admittance do you
8 have any objection to these documents?

9 MR. MERRILL: No, no objection to the
10 admittance of these affidavits, Your Honor.

11 [Respondent's Exhibits 92, 93, 94 and 95
12 admitted into evidence.]

13 H.O. LEUNG: Okay, Mr. Merrill, do you want
14 to respond to those?

15 MR. MERRILL: I think Dr. Rosen did that.

16 H.O. LEUNG: Okay.

17 MR. MERRILL: I would put just on the --
18 she didn't respond to the medic-, the religious
19 exemption [unintelligible] [13:11].

20 H.O. LEUNG: Okay. If there's nothing
21 further from either side, I have enough to make a
22 decision as to this summons. Mr. Siri, do you have
23 anything further?

24 MR. SIRI: No, Your Honor.

25 [END OF HEARING]

CERTIFICATE OF ACCURACY

I, Devin Turpin, certify that the foregoing transcript of Department of Health and Mental Hygiene v. Judith Fried on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Devin Turpin

Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>JUDITH FRIED 42 WALTON STREET, APT.#3A BROOKLYN, NY 11206</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30304-19L0</u></p> <p>Decision Date: <u>9/25/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
---	--

Summary Disposition: **Sustained**

LINE ITEM	VIOL CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on May 10, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

Debra

			<p>in Williamsburg, Brooklyn, which included zip code 11206 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of May 10, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
--	--	--	--	--	--

D. J. [Signature]

			<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent provided an affidavit stating that the child's siblings suffered "moderate to severe adverse vaccine reactions." (R92) Dr. Rosen testified that the fact that a sibling suffered an adverse reaction to the MMR vaccine is not a medical justification to withhold the MMR vaccine. Petitioner also argued that Respondent did not meet its burden in showing a medical exemption because a doctor's note was not provided by Respondent. I credit Dr. Rosen's testimony as it pertains to this issue and find that Respondent did not meet its burden in showing that a medical exemption applied because a doctor's note was not provided.</p> <p>Respondent also submitted an affidavit attesting to Respondent's religious objection to the MMR vaccine. (R95). Petitioner replied that a religious objection is not a valid defense to the allegations. I credit Petitioner's testimony and argument pertaining to this issue.</p> <p>Respondent also argued that service was improper because service was made at 11:15 p.m. Respondent could not cite a section of law or any case law which supports the proposition that service at 11:15 p.m. is improper. I find that there is no statutory provision or case law which supports a finding that service in this case, made at 11:15 p.m., was improper.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
--	--	--	--	--	--

Dell J...

					TOTAL:	\$1,000.00
--	--	--	--	--	---------------	-------------------

Dell L...

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- **To pay by mail**, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- **To pay in person**, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
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**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division within 30 days of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

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**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received within 30 days of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

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613c Decision Back Health 5-4-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Judith Fried

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30304-19L0

NOTICE OF APPEAL

Respondent Judith Fried (“Mrs. Fried”) hereby appeals the decision on Summons Number 30304-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mrs. Fried submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On May 13, 2019, Mrs. Fried was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child H.F. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mrs. Fried of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On May 13, 2019 Mrs. Fried was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Fried's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER'S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on May 13, 2019, alleges a violation that occurred on May 10, 2019, which is after the Commissioner's Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Fried alleges a violation of the Commissioner's Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner's Order. The Commissioner's Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Fried violated the Commissioner's Order on May 10, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner's Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously; occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was May 10, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MRS. FRIED AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Fried. Due process requires that Mrs. Fried be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." Petitioner-Appellee's Hearing Exhibit 2.

meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Fried be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Fried from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside**, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. See, argument at Section I, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Fried must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Fried is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Fried of mounting a viable defense to the Summons. Furthermore, Mrs. Fried was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Fried an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FRIED OF A FULL AND FAIR HEARING BY

**REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER
WHERE A DISPUTE OF FACT WAS PRESENTED**

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Fried of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Fried proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Fried’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“Dr. Rosen”), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14**. However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child’s address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Fried to determine if the child had been given MMR before the Summons was issued (**Hearing**

Transcript, p 117-118).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Fried the ability to cross-examine the issuing officer and deprive Mrs. Fried of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FRIED OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Fried of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Fried's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mrs. Fried's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Fried of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Fried's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Fried “*relied upon* the last paragraph of the Order, which states, ‘[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board’” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Fried did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mrs. Fried’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mrs. Fried read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Fried paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Fried made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Fried made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this

conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Fried as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mrs. Fried was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE IT WAS ARBITRARY AND CAPRICIOUS FOR THE HEARING OFFICER TO SUSTAIN A SUMMONS MANDATING A VACCINATION FOR A CHILD UNDER TWELVE MONTHS OLD WHERE THE FOOD AND DRUG ADMINISTRATION HAS NOT LICENSED THAT VACCINATION FOR CHILDREN UNDER TWELVE MONTHS OLD

The Tribunal should dismiss the Summons because it was arbitrary and capricious for the

Hearing Officer to sustain the Summons mandating the MMR vaccine for a child less than twelve months old. Mrs. Fried's child was less than twelve months old at the time of the alleged violation. **Respondent-Appellant's Hearing Exhibit 93, Declaration of Judith Fried, Child's Date of Birth.** The Food and Drug Administration ("FDA") has not licensed MMR for children less than twelve months old. Mrs. Fried presented undisputed evidence at the hearing that the MMR vaccine is not licensed for this age group and that the "safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established." **Respondent-Appellant's Hearing Exhibit 30.** Therefore, the Summons and the Hearing Officer's order are both saying that Mrs. Fried's child must receive a vaccination even though the FDA has not determined that it is safe and effective for the child. This is patently arbitrary and capricious because there is no reasonable basis for the Hearing Officer to uphold a violation for failure to vaccinate a child with MMR where the vaccine is not licensed for use in the child.

Finally, the Hearing Officer failed to address this argument in his written decision, further making the decision arbitrary and capricious.

VII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine ("IOM"), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 - *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 - CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 – Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 – British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 – NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* (“M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility”).

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert “transverse myelitis” in 2014 and “Henoch-Schonlein purpura” and “acute hemorrhagic edema of infancy” in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule – United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal. Additionally, Mrs. Fried submitted sufficient evidence that her other children have suffered from moderate to severe adverse vaccine reactions. **Respondent-Appellant's Hearing Exhibit 92, Declaration of Judith Fried, Adverse Reaction.**

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VIII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Fried reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Dated: November 30, 2019

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Attorneys for Respondent-Appellant

**DOHMH v. Judith Fried
30304-19L0**

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30304-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

III. The hearing officer did not deprive the Respondent a full and fair hearing by declining to order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an

Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted." The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

V. The Summons should not be dismissed because Respondent alleges the hearing officer's decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that "the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law."

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer's findings, however, that is not grounds to reverse the decision. It has been held that "[w]here evidence conflicts and a Hearing Officer's decision is based on the credibility of the evidence presented, the Hearing Officer's decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance." *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C

(November 15, 2019), *citing Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges it is arbitrary and capricious for the hearing officer to sustain the Summons

Respondent provides no basis for their constitutional argument that this Tribunal cannot sustain a summons that requires a child under twelve months be vaccinated since the decision is arbitrary and capricious and lacks rational basis. We agree with Respondent that constitutional arguments are beyond the scope of the Tribunal (Appeal page 19, footnote 19) but the Summons does not require constitutional conclusions to be decided.

The violation in the Summons is within the jurisdiction of the Tribunal as provided in Title 48, § 6-02, which states that “the Tribunal has jurisdiction to hear and determine summonses alleging non-compliance with the provisions of the Health ... relating to or affecting health within the City and any other laws or regulations that the Department of Health and Mental Hygiene has the duty or authority to enforce.”

Accordingly, the decision should be affirmed.

VII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VIII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 19, footnote 7), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy*

Center, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
 Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>JUDITH FRIED 42 WALTON STREET, APT.#3A BROOKLYN, NY 11206</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30304-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: **AFFA**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
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Appeal No. 30304-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30304-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 13, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 10, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that all the arguments made and evidence submitted in the hearing previously

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. For this hearing, Respondent asked that the summons be dismissed because it was served in person after 11:00 P.M., which Respondent argued was improper. In addition, Respondent argued that the measles vaccine was not licensed for children under 12 months of age, and submitted declarations that the child's sibling previously suffered from moderate to severe adverse vaccine reaction and that the parent has a religious objection to the vaccination.⁶ The declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was in violation of the Resolution, which itself constituted an order under HC § 3.05, for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁸ The DOHMH doctor testified that the Advisory Committee on Immunization Practices,⁹ which sets the national standards for vaccination, states that during an outbreak, MMR vaccine may be used for children ages six to eleven months and recommends vaccinating children in that age group prior to international travel.¹⁰ She testified that the Advisory Committee does not consider reactions in siblings to be a

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ In the audio record, these declarations are referred to as affidavits, but the record does not show that they were sworn to.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in an earlier hearing, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

¹⁰ "MMR" stands for Measles, Mumps, Rubella.

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contraindication, and pointed out that the parent did not submit documentation of a medical exemption for the child. Petitioner's counsel also noted that the claim for religious exemption is not a legal defense.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. He credited the testimony of the DOHMH physician that an adverse reaction to the MMR vaccine suffered by a sibling is not a medical justification to withhold the vaccine, and that a medical exemption was not established because Respondent did not provide a doctor's note. He also found that a religious objection was not a valid defense to the charge. The hearing officer rejected Respondent's assertion that service was improper because it was made at 11:15 P.M. as Respondent could not cite any regulation or case law to support that argument. He credited the allegations contained in the summons and found that they support a violation of the cited section of law. He found that Respondent had failed to provide a defense and sustained the charge.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹¹ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which in this case would include Respondent's objections on religious grounds.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct in finding that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

¹¹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order

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being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn, and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 10, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹²

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹³ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically

¹² In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹³ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

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DOHMH v. J. Doe

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for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁴ Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁴ See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30373-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: SIMON JOSEF ID NUMBER: 50093812

ADDRESS: 217 KEAP ST #4L BROOKLYN, NY 11211 PHONE:

DATE AND TIME OF OCCURRENCE: June 4, 2019 AT 9:30 AM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 217 KEAP ST #4L BROOKLYN, NY 11211

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 18, 2019 AT 11:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan, Staten Island, Bronx, Queens, Brooklyn (checked) with addresses: 66 John Street, 350 St. Marks Place, 3030 Third Avenue, 31-00 47th Avenue, 9 Bond Street.

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED.

REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 2 columns: Code Section, Violation Description. Row 1: NYC HC 3.05, In response to the active measles outbreak in certain parts of Brooklyn, the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order.

NYC Charter Sections 1048 and 1049-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice. I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Signature of Pooja Jani, Date 06/04/2019. I acknowledge that I have received a copy of this Summons and instructions for responding and that I am authorized to accept service of this Summons. Received by: Print Name, Signature, Title, Date.

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is **NOT** marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,
 Petitioner,

Summons No.
30373-19L0

- against -

SIMON JOSEF,

Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVE
DEPARTMENT OF HEALTH & MENTAL HYGIENE

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

PETITIONER'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

RESPONDENT'S					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
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96.	Religious exemption affidavit	5	
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PROCEEDINGS

4

1 H.O. DAVID LEUNG: Okay. We're on the
2 record. Today's date is September 25, 2019. It's
3 11:23 in the morning. We're here today on the
4 Department of Health issued Summons No. 30373-19L0,
5 MMR Vaccination summons issued by the Department of
6 Health. We have an attorney for DOH here.

7 MR. THOMAS MERRILL: Thomas Merrill.

8 H.O. LEUNG: And we also have an attor-, I'm
9 sorry, a physician from Department of Health.

10 DR. JENNIFER ROSEN: Jennifer Rosen.

11 H.O. LEUNG: Dr. Rosen, do you swear or
12 affirm the testimony you give will be the truth?

13 DR. ROSEN: Yes.

14 [WHEREUPON THE WITNESS, J E N N I F E R
15 R O S E N, WAS DULY SWORN.]

16 H.O. LEUNG: Thank you. And for Respondent?

17 MR. AARON SIRI: Aaron Siri.

18 H.O. LEUNG: Mr. Siri, do you waive the need
19 for translation? Do you understand the penalty
20 carries -- the cited section of law carries a penalty
21 of \$1,000, that both sides have a right to appeal,
22 and that you have a right to have the summons read,
23 read out, which you waive. Is that correct?

24 MR. SIRI: Yes, Your Honor.

25 H.O. LEUNG: Okay. do you incorporate the

PROCEEDINGS

5

1 evidence, testimony and documents provided in
2 previous hearing 30198-19L0?

3 MR. SIRI: I do, as well as the arguments
4 therein.

5 H.O. LEUNG: Department of Health, any
6 objection to that?

7 MR. MERRILL: No objection for the sake of
8 efficiency relying on the [unintelligible] [00:01:09]
9 record.

10 H.O. LEUNG: Okay. Since Mr. Siri has
11 waived the formal reading of the summons, I'm going
12 to turn to Department of Health.

13 MR. MERRILL: Your Honor, we've gotten a
14 Board of Health resolution and the Commissioner's
15 Order were part of the totality of record. In this
16 case, the registering was checked at June 4th. The
17 infant child was [unintelligible] [00:01:28] time and
18 was not vaccinated despite the [unintelligible]
19 [00:01:32].

20 H.O. LEUNG: Mr. Siri?

21 MR. SIRI: The only additional defense is
22 that this parent has a religious objection to
23 providing the measles vaccine to their child.

24 H.O. LEUNG: I'm going to mark this
25 religious exemption affidavit as Respondent's 96.

PROCEEDINGS

6

1 Any objection to this coming into the record, Mr.
2 Merrill?

3 MR. MERRILL: I have no objection to it
4 coming in, Your Honor.

5 H.O. LEUNG: Okay. And just on the record,
6 how would you like to respond to this?

7 MR. MERRILL: I would just respond it does
8 not affect the order and violation.

9 H.O. LEUNG: Is there anything else you want
10 to add, Mr. Siri?

11 MR. SIRI: Can we just see the affidavit of
12 service?

13 H.O. LEUNG: Oh, sure.

14 MR. SIRI: Thank you. Thank you. Nothing
15 further, Your Honor, on this one.

16 H.O. LEUNG: Okay. I have enough to make a
17 decision. Both sides will receive my written
18 decision within 30 days. Thank you.

19 [END OF HEARING]

CERTIFICATE OF ACCURACY

I, Devin Turpin, certify that the foregoing transcript of Department of Health & Mental Hygiene v. Simon Josef on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Devin Turpin

Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018


OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
 Hearings Division

 9 Bond Street, 7th Floor
 Brooklyn, NY 11201

DECISION

<p style="text-align: center;">DEPARTMENT OF HEALTH & MENTAL HYGIENE,</p> <p style="text-align: center;">-against-</p> <p style="text-align: center;">SIMON JOSEF 217 KEAP STREET, #4L BROOKLYN, NY 11211</p> <p style="text-align: center;">(Respondent)</p>	<p>Violation/Summons No.: <u>30373-19L0</u></p> <p>Decision Date: <u>9/25/2019</u></p> <p>Hearing Officer: <u>Leung David</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>In Person</u></p>
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 Summary Disposition: **Sustained**

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on June 4, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

			<p>in Williamsburg, Brooklyn, which included zip code 11211 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of June 4, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
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				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent submitted an affidavit attesting to Respondent's religious objection to the MMR vaccine. (R96) Petitioner replied that a religious objection is not a valid defense to the allegations.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I credit respondent's evidence but find that it does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>		
					TOTAL:	\$1,000.00

D. J. [Signature]

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance, Comptroller, P.O. Box 4199, Church Street Station, New York, NY 10281-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCEP # 20 on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division located at:
 - Manhattan at 60 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-60 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/nyllicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit cards transactions.

**IF YOU
DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division **within 30 days** of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received **within 30 days** of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

For more information,
see OATH's website nyc.gov/oath
or call 1-844-OATH-NYC

GH0c Decision Back Health 5-9-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Simon Josef

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30373-19L0

NOTICE OF APPEAL

Respondent Simon Josef (“**Mr. Josef**”) hereby appeals the decision on Summons Number 30373-19L0 (the “**Summons**”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “**Commissioner**”) issued an Order (the “**Commissioner’s Order**”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“**MMR**”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “**Board**”) created a resolution (the “**Resolution**”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mr. Josef submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On June 4, 2019, Mr. Josef was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for his child H.P.J. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mr. Josef of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On June 4, 2019 Mr. Josef was cited as having violated the Commissioner's Order by failing to vaccinate his child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "Hearing Officer") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mr. Josef's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on June 4, 2019, alleges a violation that occurred on June 4, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mr. Josef alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mr. Josef violated the Commissioner’s Order on June 4, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. Exhibit C, Hearing Transcript, p 58. The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board may *amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously; occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration of[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was June 4, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED TO PROVIDE REASONABLE NOTICE TO MR. JOSEF AS REQUIRED BY DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mr. Josef. Due process requires that Mr. Josef be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2.**

meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mr. Josef be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷ **Petitioner-Appellee's Hearing Exhibit 2.** Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mr. Josef from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles."

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside**, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2.** (emphasis added.) The distinction between the words "live" and "reside" are legally significant. See, argument at Section L, p 5.

Exhibit A, Summons. This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mr. Josef must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mr. Josef is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mr. Josef of mounting a viable defense to the Summons. Furthermore, Mr. Josef was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mr. Josef an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. JOSEF OF A FULL AND FAIR HEARING BY

**REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER
WHERE A DISPUTE OF FACT WAS PRESENTED**

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Josef of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

“A respondent may request the [issuing officer’s] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful.” *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mr. Josef proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mr. Josef’s application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen (“Dr. Rosen”), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14**. However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child’s address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mr. Josef to determine if the child had been given MMR before the Summons was issued (**Hearing Transcript,**

p 117-118).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mr. Josef the ability to cross-examine the issuing officer and deprive Mr. Josef of a full and fair hearing, and the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MR. JOSEF OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mr. Josef of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mr. Josef's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240.** In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153.** Therefore, the Hearing Officer committed an error of law by preventing Mr. Josef's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mr. Josef of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mr. Josef's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mr. Josef “*relied upon* the last paragraph of the Order, which states, “[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board”” to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mr. Josef did not *rely upon* this statement made in the Commissioner’s Order. Instead, Mr. Josef’s argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner’s Order. In fact, counsel for Mr. Josef read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mr. Josef paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mr. Josef made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer’s authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p 151 p 172; p183.** Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mr. Josef made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this

conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mr. Josef as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and is not factually supported; hence, Mr. Josef was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo

cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 – NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mr. Josef reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *ILC. v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Dated: November 30, 2019

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DOHMH v. Simon Josef
30373-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") See *DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30373-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. See e.g. Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); c.f. Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged ...; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*, Appeals No. 10087317C (March 12, 2018) ("Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.").

Accordingly, the decision should be affirmed.

III. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, "Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector's testimony is likely to be necessary to a

fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

V. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VI. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5) (“...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent’s appeal.

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As Respondent concedes in their appeal (page 18, footnote 9), Respondent’s Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C’s Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>SIMON JOSEF 217 KEAP STREET, #4L BROOKLYN, NY 11211</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30373-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
---	--

Summary Disposition: AFFA

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	Affirmed.	Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
 Telephone: (212) 436-0624
 Fax: (212) 436-0714

Appeal No. 30373-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30373-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on June 4, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by his attorney. Petitioner was represented by its general counsel and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, Respondent submitted a copy of the parent/guardian statement prepared in connection with his request to the State Education Department for religious exemption from immunization. The statement was taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was in violation of the Resolution, which itself constituted an order under HC § 3.05, for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁶ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*, denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds.⁷ Petitioner asserted that a religious objection was not a defense to the Order. Petitioner also noted that the subject child was non years old.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. In addition, he found that a religious objection was not a valid defense to the charge. The hearing officer credited the allegations contained in the summons and found that they supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.⁸ Respondent argues that he did not have a full and fair hearing because he

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁷ See 2019 NY Slip Op 31047 (April 18, 2019).

⁸ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert.⁹ Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct in finding that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that while HC § 3.01(d) allows the BOH to continue the Order as is, it does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the

⁹ "MMR" stands for Measles, Mumps, Rubella.

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Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found that they supported a violation of the cited section of law. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17,

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DOHMH v. J. Doe

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2019. Respondent argues that the summons must be dismissed because it was issued after April 17, when the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on June 4, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹⁰

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹¹ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹² Respondent did not offer proof to contest any of the essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

¹⁰ In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹¹ See *DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹² See *Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness, and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).

SUMMONS NUMBER: 30328-19L0

ENFORCEMENT AGENCY NAME: DEPT. OF HEALTH AND MENTAL HYGIENE

DIVISION: Disease Control BUREAU: Immunization

AGENCY ADDRESS AND PHONE NUMBER: 42-09 28th Street, Long Island City, NY 11101 Phone: 347-396-7998

RESPONDENT: Chanie Fulop ID NUMBER: 50093122

ADDRESS: 115 Wallabout St, Brooklyn, NY, 11206 PHONE:

DATE AND TIME OF OCCURRENCE: May 22, 2019 AT 12:20 PM BOROUGH: Brooklyn

PLACE OF OCCURRENCE : 115 Wallabout St, Brooklyn, NY, 11206

The respondent is summoned to appear and respond to the details of violation(s) stated below.

HEARING DATE: July 10, 2019 AT 11:00 AM

** RESPONDENT MUST APPEAR IN PERSON **

OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS:

- Manhattan 66 John Street 10th & 11th Floor New York, NY 10038
Staten Island 350 St. Marks Place Main Floor Staten Island, NY 10301
Bronx 3030 Third Avenue Room 250 Bronx, NY 10455
Queens 31-00 47th Avenue 3rd & 4th Floor Long Island City, NY 11435
XX Brooklyn 9 Bond Street 6th & 7th Floor Brooklyn, NY 11201

INSTRUCTIONS FOR RESPONDING TO THIS SUMMONS ARE ON THE BACK OF THIS PAGE OR ATTACHED. REFER TO THE SUMMONS NUMBER ABOVE ON ALL CORRESPONDENCE.

WARNING: If you do not show up for your hearing (or pay the penalty by mail if permitted) the Summons will be decided against you and penalties will be imposed. Your license may also be suspended or revoked. In addition, the City may enter a judgment against you in court.

Details of Violation(s)

Table with 3 columns: #, Code Section, Violation Description. Row 1: 1, NYC HC 3-05, In response to the active measles outbreak in certain parts of Brooklyn the NYC Commissioner of Health declared a public health emergency on April 9, 2019 and published a Commissioner's Order ("Order") pursuant to Article 3 of the NYC Health Code ordering all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles within forty eight hours of the Order. On April 17, 2019, the NYC Board of Health unanimously approved a Resolution ("Resolution") continuing the public health emergency and requirement that all persons living, working or attending school in these affected ZIP codes be vaccinated against measles. The Resolution further provides that any person who is not vaccinated, or the parent and/or guardian of a child who is not vaccinated, shall be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate. A copy of the Order and Resolution are attached to this Summons for reference. A review of Department records shows that Respondent's child, D.F., who is at least six months old, lives at: 115 Wallabout St, Brooklyn, NY, 11206, which is located in one of the affected zip codes listed in the Order. On May 22, 2019, a review of the Department's Citywide Immunization Registry, which collects immunization records for all children receiving vaccines in NYC and is required to be updated by medical providers, found that child D.F. has no record of measles immunization. Respondent has failed to vaccinate child D.F. or otherwise submit acceptable proof of immunity in violation of the Order.

NYC Charter Sections 1048 and 1048-a and the Rules of the City of New York authorize the NYC Office of Administrative Trials and Hearings (OATH) to hold hearings. For hearing options, see other side of this notice. I, an employee of the agency named above, affirm under penalty of perjury that I personally observed the commission of the violation(s) charged above and/or verified their existence through a review of departmental records. False statements made herein are punishable as a Class A Misdemeanor pursuant to section 210.45 of the Penal Law.

Signature and Date fields for Poola Jani, dated 05/23/2019. Received by: fields for Print Name, Signature, Title, Date.

The agency named on the front of this Summons has alleged that you committed the described violation or violations. Note: If the charge on the front of the Summons states you **MUST APPEAR IN PERSON**, then you or an authorized representative must attend the hearing in person. See the front of this Summons for the date, time and location of your hearing. In some cases, the agency may offer you the chance to enter into a stipulation or settlement agreement. If you are eligible, the agency will send you a letter in the mail. To accept the stipulation or settlement, follow the instructions in the letter.

If a stipulation or settlement is offered to you and you do not accept it, the independent NYC Office of Administrative Trials and Hearings will hear and decide your case. If you do not accept the settlement or show up for your hearing, a default judgment may be entered against you and additional penalties may be imposed.

If your case is NOT marked "MUST APPEAR IN PERSON," you may deny the charges or their severity by presenting a defense online, by phone or by mail.

- Online: To submit a defense online, visit www.nyc.gov/oath.
- Phone: To schedule a hearing by phone, call (212) 436-0817.
- Mail: To submit a defense by mail, send a signed statement of facts that must say, "My signature in this statement certifies that all facts in it are true," with all documents you wish to have considered to: OATH Mail Unit, 66 John Street, 10th Floor, New York, NY 10038.

To present a defense in person:

- You or an authorized representative must appear in person on the hearing date at the time and location on the front of this Summons.
- If no location is listed or checked off, you may appear at any OATH Hearings Center on the date and time indicated on this Summons (see locations below).
- Please be fully prepared for a hearing at that time by bringing this Summons and all of your evidence with you.
- If you require assistance with English, free language assistance will be provided.

Reasonable Accommodation: If you have a disability and require a reasonable accommodation on the day of your hearing, call the phone number listed below.

Note: YOU HAVE THE RIGHT TO BE INFORMED OF THE MAXIMUM PENALTY. Pursuant to the New York City Health Code, §3.11, a penalty of not less than \$200 and not more than \$2000 may be imposed for each Health Code violation. For non-NYCHC violations please see the cited statute/regulation for maximum penalties. The penalty for certain violations may be found in regulations available at nyc.gov/health. Higher penalties may be imposed for each repeated violation up to the maximum penalty allowed by law or regulation.

OATH HEARINGS CENTERS

Tel: 1-844-OATH-NYC (1-844-628-4692) www.nyc.gov/oath

Manhattan: 66 John Street, 10th & 11th Floors, New York, NY 10038

Brooklyn: 9 Bond Street, 7th Floor, Brooklyn, NY 11201

Queens: 31-00 47th Avenue, 3rd Floor, Long Island City, NY 11435

Bronx: 3030 Third Avenue, Room 250, Bronx, NY 10455

Staten Island: 350 St. Mark's Place, Main Floor, Staten Island, NY 10301

THE CITY OF NEW YORK
OFFICE OF ADMINISTRATIVE
TRIALS AND HEARINGS

P R E S E N T: DAVID LEUNG
 Hearing Officer

In the matter of:

DEPARTMENT OF HEALTH & MENTAL HYGIENE,
 Petitioner,

Summons No.
30328-19L0

- against -

CHANIE FULOP,
 Respondent.

September 25, 2019

Office of Administrative Trials
And Hearings
100 Church Street
New York, NY 10007

A P P E A R A N C E S:

THOMAS MERRILL, ESQ.
JENNIFER ROSEN, MD
PETITIONER'S REPRESENTATIVE
Department Of Health & Mental Hygiene

AARON SIRI, ESQ.
RESPONDENT'S REPRESENTATIVE

I N D E X

3

<u>PETITIONER'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>
<u>RESPONDENT'S</u>					<u>VOIR</u>
<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIR</u>	<u>RECROSS</u>	<u>DIRE</u>

E X H I B I T S

<u>H.O.</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
<u>PETITIONER</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
26.	Affidavit of Service		7
<u>RESPONDENT</u>	<u>DESCRIPTION</u>	<u>I.D.</u>	<u>IN EV.</u>
98.	Affidavit		6
89.	Declaration from respondent		6
100.	Service declaration		6

PROCEEDINGS

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1 H.O. DAVID LEUNG: Okay. We are on the
2 record. It's September 25, 2019, 11:36 in the
3 morning. We are at the Brooklyn OATH location. My
4 name is David Leung, Hearing Officer. We are here
5 today on summons 30328-19L0 issued to Chanie Fulop.
6 We have a representative from the Department of
7 Health here, the attorney. What is your name, sir?

8 MR. THOMAS MERRILL: Thomas -- I'm Thomas
9 Merrill, General Counsel.

10 H.O. LEUNG: We also have a physician from
11 Department of Health?

12 DR. JENNIFER ROSEN: Jennifer Rosen.

13 H.O. LEUNG: Dr. Rosen, do you swear or
14 affirm the testimony you give will be the truth?

15 MS. ROSEN: Yes.

16 [WHEREUPON THE WITNESS, J E N N I F E R R
17 O S E N, WAS DULY SWORN.]

18 H.O. LEUNG: Thank you. And for
19 respondent?

20 MR. AARON SIRI: Aaron Siri.

21 H.O. LEUNG: Mr. Siri, do you waive the
22 need for an interpreter? Do you understand the
23 penalty for this violation is \$1,000? Do you
24 understand both sides have a right to appeal and do
25 you waive a formal reading of the allegations?

PROCEEDINGS

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1 MR. SIRI: I do, Your Honor.

2 H.O. LEUNG: Do you incorporate the
3 evidence and arguments that you made under summons
4 number, I forgot the number, if you remember it,
5 30198-19L0?

6 MR. SIRI: I do.

7 H.O. LEUNG: Any objection to those
8 documents and arguments in evidence coming in,
9 Department of Health?

10 MR. MERRILL: No, Your Honor. For the sake
11 of efficiency, we agree to use the Saturday record.

12 H.O. LEUNG: Okay. And Mr. Merrill, I'm
13 going to turn to you now.

14 MR. MERRILL: Okay, Your Honor. Again, the
15 Board of Health resolution and the Commissioner's
16 order are part of the consolidated record. In this
17 case the immunization registry was checked on May
18 22nd as the child was not immunized as of that date
19 and was living in one of the infected measles areas.

20 H.O. LEUNG: Mr. Siri?

21 MR. SIRI: I have three additional
22 defenses. One is that the child was under 12 years
23 of age and there was no license --

24 H.O. LEUNG: Twelve months, 12 months.

25 MR. SIRI: Twelve months, excuse me, thank

PROCEEDINGS

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1 you, 12 months of age and there is no licensed
2 measles vaccine for a child under 12 months of age.
3 The doctor has previously stated while the Advisory
4 Committee on Immunization Practices recommends during
5 an outbreak that a child receive it despite the fact
6 it's not licensed but I point out again that that's a
7 recommendation. It does not say mandate.

8 H.O. LEUNG: Do you have an affidavit as
9 you are testifying so I can mark it?

10 MR. SIRI: Yeah, absolutely. And then I
11 also -- second is a religious argument and we have a
12 declaration from the respondent regarding their
13 religious beliefs against providing a measles vaccine
14 to their child. And the last one is, it's, it's a
15 service issue and in fact the, the client did have
16 the summons taped to their door. So, they did the
17 nail part but they say they never received a copy in
18 the mail. And so, we have a declaration on that
19 point.

20 H.O. LEUNG: Any objection to 98, 99 --

21 MR. MERRILL: No objection.

22 H.O. LEUNG: -- and 100 coming in?

23 MR. Merrill: No objection, Your Honor.

24 H.O. LEUNG: Okay.

25 **[Respondent's Exhibits 98, 99 and 100**

PROCEEDINGS

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1 **admitted into evidence.]**

2 MR. MERRILL: So, in response, one, I'll
3 hand up now the Affidavit of Service, it is mail in
4 mail service and there is an affidavit from the
5 Deputy Sheriff saying -- attesting that, not only did
6 he tape it to the door, but he also mailed it on June
7 5th.

8 H.O. LEUNG: Okay. I'm going to mark this
9 as Petitioner's 26. Is there any objection to this
10 Affidavit of Service coming in?

11 MR. SIRI: No, Your Honor.

12 H.O. LEUNG: Okay.

13 **[Petitioner's Exhibit 26 admitted into**
14 **evidence.]**

15 MR. MERRILL: In response to the religious
16 exemption, as, as I've already said in other cases,
17 it's just not a defense to this, to this order or
18 requirement and I'll turn over to Dr. Rosen in the
19 last defense.

20 DR. ROSEN: So, with regard to the
21 vaccinating between age six to 11 months, the
22 Advisory Committee on Immunization Practices which
23 sets the national recommendations for vaccinations
24 recommends vaccination at six to 11 months prior to
25 international travel, for all infants travelling and

PROCEEDINGS

8

1 recommends that MMR be considered during an outbreak
2 in addition to the Commissioner's order which
3 mandated vaccination for this age group.

4 H.O. LEUNG: Okay. I have enough to make a
5 decision as to this case. Hearing nothing further
6 from both sides, this hearing is closed. Thank you.

7 [END OF HEARING]

8

CERTIFICATE OF ACCURACY

I, Claudia Marques, certify that the foregoing transcript of Department of Health & Hygiene v. Chanie Fulop on September 25, 2019 was prepared using the required transcription equipment and is a true and accurate record of the proceedings.

Certified By

Claudia Marques

Date: November 9, 2020

GENEVAWORLDWIDE, INC

256 West 38th Street - 10th Floor

New York, NY 10018


OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
 Hearings Division

 9 Bond Street, 7th Floor
 Brooklyn, NY 11201

DECISION

DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against- CHANIE FULOP 115 WALLABOUT STREET BROOKLYN, NY 11206 (Respondent)	Violation/Summons No.: <u>30328-19L0</u> Decision Date: <u>9/25/2019</u> Hearing Officer: <u>Leung David</u> Respondent's Rep.: <u>Aaron Siri, Esq.</u> Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u> Type of Hearing: <u>In Person</u>
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 Summary Disposition: Sustained

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05	<p>The summons alleges that on May 22, 2019, Respondent, the parent of a child who is at least 6 months old, failed to comply with the Commissioner's Order, in violation of NYC Health Code 3.05.</p> <p>Petitioner introduced a copy of the Commissioner's Order (P1) and the Health Board's Resolution (P2), dated April 9, 2019 and April 17, 2019 respectively, wherein the Commissioner declared, and the Board resolved, that a public health emergency existed pursuant to NYC Health Code 3.01. The Commissioner, by her Order, and the Board, by its Resolution, directed that persons six months of age or older who live, work or reside in certain zip codes</p>	Sustained	\$1,000.00

Summons#: 30328-19L0

09/25/2019

				<p>in Williamsburg, Brooklyn, which included zip code 11206 (respondent's zip code), be vaccinated against measles, demonstrate immunity to measles, or show proof of an acceptable medical exception.</p> <p>Petitioner relied upon the sworn statements of the issuing inspector, and the evidence submitted at the hearing.</p> <p>Respondent argued that the Commissioner's Order (P1), expired on April 17, 2019, and that the summons, which alleges an occurrence date of May 22, 2019, must therefore be dismissed because Respondent cannot be liable for violating an expired Order.</p> <p>In support of this argument, Respondent relied upon the last paragraph of the Order, which states, "This Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board."</p> <p>I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.</p> <p>Respondent made a variety of constitutional and scientific arguments and challenges to the validity of the summons and the MMR vaccine, the efficacy and safety of the MMR vaccine, and the fundamental fairness of requiring the MMR vaccine. In support of these arguments, Respondent provided substantial documentation. (Respondent's 1 to 45).</p> <p>Petitioner responded by stating that the validity and efficacy of the MMR vaccine and the Commissioner's authority to issue an emergency Order was settled in recent litigation. (P4 is a copy of a decision by Hon. Lawrence Knipel, which ruled on these issues).</p> <p>I find that Respondent's constitutional and scientific arguments</p>		
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				<p>are beyond the scope of the hearing, and accordingly, I make no findings as to the validity of Respondent's evidence or arguments in these areas.</p> <p>On the merits of the case, Respondent provided an affidavit stating that the child is under 12 months of age (R98) and argued that the MMR vaccine isn't licensed for children under the age of 12 months. In response, Dr. Rosen testified that in emergency/outbreak situations, an MMR vaccine is appropriate for a child older than six months. I credit Dr. Rosen's testimony as it pertains to the issue of the safety and efficacy of the MMR vaccine for a child under the age of 12 months.</p> <p>Respondent provided an affidavit stating that although a copy of the summons was taped to Respondent's apartment door, she never received a copy in the mail. (R100) In response, Petitioner provided a copy of the Certificate of Service and Mailing. (P26) I credit Petitioner's Certificate of Service and find that a copy of the summons was properly mailed to Respondent's address.</p> <p>Respondent also submitted an affidavit attesting to Respondent's religious objection to the MMR vaccine. (R101). Petitioner replied that a religious objection is not a valid defense to the allegations. I find that Respondent's religious objection to the MMR vaccine is not a valid defense to the allegations.</p> <p>I credit the allegations contained in the summons and find that they support a violation of the cited section of law. I find that Respondent's evidence and testimony does not provide a defense to the allegations. Line Item 1 is sustained and the statutory civil penalty of \$1,000 is imposed.</p>			
						TOTAL:	\$1,000.00

D. J. [Signature]

**IF YOU ARE FOUND IN VIOLATION, YOU MUST
PAY THE PENALTY WITHIN 30 DAYS OF THE
DECISION DATE OR 35 DAYS IF MAILED.**

- To pay by mail, send a check or money order to the Dept. of Finance Commissioner, PO Box 4199, Church Street Station, New York, NY 10261-4199. The check or money order should be made out to "Finance Commissioner, City of New York." Write the summons number and ACCELA ID on the check or money order.
- To pay in person, bring a check, money order or credit card and this decision to the OATH Hearings Division locations in:
 - Manhattan at 66 John Street, 11th floor, New York, NY
 - Brooklyn at 9 Bond Street, 6th floor, Brooklyn, NY
 - Queens at 31-00 47th Avenue, 3rd floor, Long Island City, NY
- To pay online using a credit or debit card, go to nyc.gov/mylicense. First time users will be required to set up a User ID, password, and request a PIN to use this service. A summons number is required to pay. Instructions are provided on the website. A service fee is charged for all credit and debit card transactions.

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DISAGREE
WITH THE
DECISION,
YOU MAY
APPEAL IT**

You **MUST** use OATH's online or mail-in appeal forms available on OATH's website to submit your appeal. Instructions for filing an appeal may be found on the form and OATH's website at nyc.gov/oath/appeals.

Your appeal **MUST** be received by the OATH Hearings Division **within 30 days** of the decision date, or 35 days if the decision was mailed to you.

To appeal you **MUST** pay the full penalty stated in this decision.

- If you cannot pay because of financial hardship, you may ask to not pre-pay by submitting with your appeal a Financial Hardship Application, also available on OATH's website.

**APPEAL BY
ENFORCEMENT
AGENCY**

If you wish to answer an appeal filed by an enforcement agency, you **MUST** use OATH's Response To Appeal form. Instructions for filing an answer may be found on the form and OATH's website at nyc.gov/appeals.

Your answer must be received **within 30 days** of the date of the enforcement agency's appeal, or within 35 days if it was mailed to you.

If the enforcement agency wins the appeal, you may have to pay a penalty even if your case was originally dismissed after the hearing.

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OATH Decision Back Health 5-4-17

CITY OF NEW YORK
DEPT. OF HEALTH AND MENTAL HYGIENE

Chanie Fulop

Respondent-Appellant,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Petitioner-Appellee

**NOTICE OF APPEAL &
MEMORANDUM OF LAW**

Summons: 30328-19L0

NOTICE OF APPEAL

Respondent Chanie Fulop (“Mrs. Fulop”) hereby appeals the decision on Summons Number 30328-19L0 (the “Summons”).¹

PRELIMINARY STATEMENT

On Friday, April 9, 2019, Oxiris Barbot, the New York City Commissioner of Health and Mental Hygiene (the “Commissioner”) issued an Order (the “Commissioner’s Order”) requiring that certain categories of people in certain zip codes be injected with Merck’s product M-M-R-II, also known as the measles, mumps, rubella (“MMR”), within forty-eight hours of the Commissioner’s Order. **Petitioner-Appellee’s Hearing Exhibit 1.**

On April 17, 2019, the Department of Health and Mental Hygiene of the City of New York Board of Health (the “Board”) created a resolution (the “Resolution”) which also required administration of the MMR vaccine, but defined what constituted a “nuisance” completely differently, applied it to different categories of individuals, had a different age range, provided for

¹ On October 25, 2019, Mrs. Fulop submitted a *Request for Extension of Time to File Appeal*. OATH approved the request on November 1, 2019, and set the deadline to file this appeal for Wednesday, December 4, 2019.

different penalties, and contained other material differences as detailed below. **Petitioner-Appellee's Hearing Exhibit 2.**

On May 23, 2019, Mrs. Fulop was cited as having violated the Commissioner's Order by not providing either proof of immunity or proof of MMR vaccination for her child D.F. (the "child"). **Exhibit A, Summons.**

The Commissioner must cautiously reserve the use of her emergency power to avoid abusing that authority. When the Commissioner and the Board flex enormous powers, the Tribunal must be comprehensive and meticulous in reviewing the Summons, hearing, and decision of the OATH Hearing Officer. The hearing record reflects that the Summons should have been dismissed and that the Hearing Officer deprived Mrs. Fulop of a full and fair hearing, made errors of law, and issued an arbitrary and capricious decision.

FACTS

On May 23, 2019 Mrs. Fulop was cited as having violated the Commissioner's Order by failing to vaccinate her child with MMR. **Exhibit A, Summons.** On September 25, 2019, David Leung (the "**Hearing Officer**") conducted a hearing concerning the Summons. The Hearing Officer sustained the Summons per decision dated September 25, 2019. **Exhibit B, Hearing Decision.** All arguments and exhibits entered into evidence during the hearing are incorporated by reference, which includes all arguments and exhibits entered into evidence for Summons Number 30198-19L0.²

² In the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on summons number 30198-19L0 into the record for Mrs. Fulop's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242.**

STANDARD OF REVIEW

“When an appeal is filed, the Appeals Unit will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law. Except as provided in 48 RCNY §§ 3-15, 5-04 and 5-05, the Appeals Unit has the power to affirm, reverse, remand or modify the decision appealed from.” 48 Rules of New York § 6-19 (g)(1).

ARGUMENT

I. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER’S ORDER EXPIRED ON APRIL 17, 2019, AND THE DATE OF OCCURRENCE ON THE SUMMONS IS AFTER THE EXPIRATION DATE

The Summons, issued on May 23, 2019, alleges a violation that occurred on May 22, 2019, which is after the Commissioner’s Order expired. Therefore, the violation was untimely, and the Tribunal must dismiss the Summons.

The Summons issued to Mrs. Fulop alleges a violation of the Commissioner’s Order. **Exhibit A, Summons.** The last sentence of the “Violation Description” section states that “Respondent has failed to vaccinate child [] or otherwise submit acceptable proof of immunity in violation of the *Order*.” *Id.* (emphasis added.) The Summons specifically defines the term “Order” as the April 9, 2019, Commissioner’s Order. The Commissioner’s Order expired on April 17, 2019. Yet, the Summons alleges that Mrs. Fulop violated the Commissioner’s Order on May 22, 2019. It was, therefore, an error of law for the Hearing Officer to affirm the Summons because the Commissioner’s Order had expired by the date of the occurrence listed on the Summons. On this basis, the Tribunal must dismiss the Summons.

During the hearing on the Summons, Petitioner-Appellee conceded that the Commissioner's Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p 58.** The Commissioner's Order expired because the New York City Health Code provides that an emergency action "shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration[.]" NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d). The Board convened on April 17, 2019; thus, the Commissioner's Order expired on that date.

During the hearing, Petitioner-Appellee argued that despite the Order expiring on April 17, 2019, the Resolution continued the Commissioner's Order, and thus the Commissioner's Order was still valid on the date of occurrence on the Summons. Petitioner-Appellee's argument is plainly incorrect. The New York City Health Code provides that "the Board *may* continue or rescind." NY City Health Code (NY City Health Code (24 RCNY)) § 3.01 (d) (emphasis added). Nothing in that section states that the Board *may amend* and continue the emergency order. On its face, that section only allows the Board to continue the order "as is" or to rescind the order and issue a new order.

In this instance, the Board did not continue the Commissioner's Order. Even though the Resolution acknowledges the Commissioner's Order in the preamble, nothing in the Resolution states it is continuing the Commissioner's Order. Instead, the Board allowed the Commissioner's Order to expire and created a new order via its Resolution dated April 17, 2019.

Indeed, the terms of the Commissioner's Order are materially different from the terms used in the Resolution. This verifies that the Commissioner's Order and the Resolution, although they both address the same topic, are two different directives, and as such, one is not a continuation of the other. *First*, the Resolution entirely redefines what constitutes a nuisance. The Order defines

the nuisance as the presence of a person unvaccinated with MMR.³ The Resolution defines the nuisance as the measles outbreak.⁴

Second, the Resolution recategorizes individuals subject to the violation in several important ways:

- a. The Commissioner's Order includes people who "live, work, or resides" in the affected zip code, but the Resolution only includes individuals who "live[] or work[]" in the affected zip codes. **Petitioner-Appellee's Hearing Exhibits 1 & 2.** The decision to not include people who "reside" in the zip code is important. Merriam-Webster's dictionary defines "reside" to mean: "to dwell permanently or continuously: occupy a place as one's legal domicile." Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/reside>. Conversely, that same dictionary defines "live" as: "to pass through or spend the duration off[.]" Merriam-Webster's Online Dictionary, *available at* <https://www.merriam-webster.com/dictionary/live>. Thus, the Commissioner's Order includes people who were not actually living in the zip codes at the time of the Order, but who maintain their legal domicile there (e.g., people who were away for the summer, or who live abroad for a period of time); in contrast, the Resolution only includes people who are physically present in the area.

³ "WHEREAS, I also find that the presence of any person in Williamsburg lacking the MMR vaccine, unless that vaccine is otherwise medically contra-indicated or such person has demonstrated immunity against measles, creates an unnecessary and avoidable risk of continuing the outbreak and is therefore a nuisance, as defined in New York City Administrative Code §17-142[.]" **Petitioner-Appellee's Hearing Exhibit 1.**

⁴ "WHEREAS, the Board of Health regards the aforesaid reports of over 300 cases of measles as sufficient proof to authorize the declaration that an outbreak of measles is occurring in Williamsburg that threatens the health and safety of New Yorkers and is immediately dangerous to human life and health and constitutes a public nuisance[.]" **Petitioner-Appellee's Hearing Exhibit 2.**

- b. The Commissioner's Order includes children "older than six months," and the Resolution includes children "six months of age and older." **Petitioner-Appellee's Hearing Exhibits 1 & 2.** Therefore, under the Commissioner's Order, children who were six months old were not required to be vaccinated, whereas, under the Resolution, six-month-old babies were required to be vaccinated.
- c. The Commissioner's Order does not include children who attend school, preschool or child care in the affected zip codes, but the Resolution does include children who "attend[] school, preschool or child care within the affected zip codes." **Petitioner-Appellee's Hearing Exhibit 2.**
- d. The Commissioner's Order exempts children whose parents or guardians provide documentation showing that MMR is not medically appropriate, whereas the Resolution is more onerous and requires that such documentation meet the satisfaction of Petitioner-Appellee.⁵

Third, the penalties are entirely different. The Commissioner's Order includes a "warning" that "[f]ailure to comply with this Order is a violation of §3.05 of the New York City Health Code, and a misdemeanor for which you may be subject to civil and/or criminal fines, forfeitures and penalties, including imprisonment." **Petitioner-Appellee's Hearing Exhibit 1.** The Resolution, however, did not include this language and opted to enhance the civil penalty by adopting the provision of NY City Health Code (24 RCNY) § 3.11 (a) and subjecting violators to fines for each family member, and for each day a person violates the Resolution. This "enhanced" civil penalty

⁵ The terminology may seem similar between the Commissioner's Order and the Resolution; however, it has a legal distinction. Otherwise, the Board would not have gone through the effort of amending the language in its Resolution.

did not appear in the Commissioner's Order but is included in the "resolved" language of the Resolution.⁶

In sum, the Resolution changes numerous legally pertinent aspects of the Commissioner's Order, including the prohibited conduct, the population subject to the order, and the penalty. This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner's Order. The Resolution plainly created a new and distinct order, and per the requirements of NY City Health Code (24 RCNY) § 3.01 (d), the Commissioner's Order expired on April 17, 2019.

For these reasons, it is evident that the Board did not continue the Commissioner's Order. The Summons cites the date of occurrence was May 22, 2019. Because the Commissioner's Order expired on April 17, 2019, prior to the date of occurrence, the Tribunal must dismiss the Summons because it was an error of law for the Hearing Officer to sustain the Summons.

II. THE SUMMONS SHOULD BE DISMISSED BECAUSE MRS. FULOP WAS NOT PROVIDED PROPER SERVICE OF THE SUMMONS

Another independent basis for dismissing the Summons exists because Mrs. Fulop was not provided proper service of the Summons. The Summons was taped to Mrs. Fulop's apartment door; however, a copy was not mailed to her via United States Postal Service. **Respondent-Appellant's Hearing Exhibit 100**. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Mrs. Fulop was not provided proper legal service, and the Tribunal must dismiss the Summons.

III. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE SUMMONS FAILED

⁶ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to reside, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declared to be over by the Commissioner of the Department of Health and Mental Hygiene." **Petitioner-Appellee's Hearing Exhibit 2**.

TO PROVIDE REASONABLE NOTICE TO MRS. FULOP AS REQUIRED BY
DUE PROCESS AND THE NEW YORK CITY CHARTER § 1046

Furthermore, the Tribunal should dismiss the Summons because it failed to provide reasonable notice to Mrs. Fulop. Due process requires that Mrs. Fulop be provided *fair notice* of the charges so that she may prepare and present an adequate defense and opportunity to be heard. *Matter of Block v. Ambach*, 73 N.Y. 2d 323 (1989). The New York City Charter requires that, at a minimum, the Summons provide an *accurate* statement of the matter to be adjudicated. NYCC § 1046. The Summons (even with the Commissioner's Order and Resolution attached) failed to meet these standards.

Because the Commissioner's Order and the Resolution are so different, due process requires that Mrs. Fulop be reasonably and accurately informed of which order she is alleged to have violated. Otherwise, Petitioner-Appellee has deprived her of the ability to mount a viable and effective defense to the allegations. For example, the Commissioner's Order and the Resolution define the term "nuisance" differently; the individuals subjected to the two orders are dissimilar; and the Commissioner's Order cites possible imprisonment, whereas the Resolution mandates civil penalties for each day the order is violated. To further complicate this issue, the Resolution enforces these civil penalties against persons who "reside" in the affected zip codes, yet the language of the Resolution itself does not mandate the MMR vaccine for individuals who "reside" in the affected zip codes – only for those who "live[] or work[] within the affected zip codes" and children who "live[] or attend[] school, preschool, or child care within the affected zip codes."⁷

⁷ "RESOLVED, that any person required by this declaration to be immunized against measles, or any parent or guardian required by it to immunize his or her child, shall be violating this order and be subject to the fines authorized by applicable law, rule and regulations each day that he, she, or such child continues to **reside**, work or attend school, preschool or child care in any of the affected zip codes without having been vaccinated against measles until such time that this outbreak is declare." **Petitioner-Appellee's Hearing Exhibit 2**. (emphasis added.) The distinction between the words "live" and "reside" are legally significant. See, argument at Section I, p 5.

Petitioner-Appellee's Hearing Exhibit 2. Therefore, the Summons (even with the Commissioner's Order and Resolution attached) does not provide fair notice of the order that was allegedly violated and as such prevents Mrs. Fulop from mounting an effective defense.

Not only does the Summons fail to provide fair notice, but it also fails provide an accurate statement of the matters to be adjudicated. The "Details of Violation" of the Summons, as sworn to by the issuing officer, refer to both the Commissioner's Order and the Resolution as *two distinct orders*. This section states that the Commissioner's Order required "all persons who live, work or attend school within ZIP codes 11205, 11206, 11211 and 11249 to be vaccinated against measles." **Exhibit A, Summons.** This representation of the Commissioner's Order is incorrect. The Commissioner's Order did not include individuals who attend school in the affected zip codes but did include people who "reside" in the affected zip codes - which the Summons fails to include.

Petitioner-Appellee's Hearing Exhibit 1.

Finally, the "Details of Violation" section of the sworn Summons summarizes the Resolution as requiring vaccination, "unless they demonstrate proof of immunity or that immunization is not *medically appropriate*." **Exhibit A, Summons.** (emphasis added.) However, the Commissioner's Order and the Resolution both state that Mrs. Fulop must demonstrate a "medical exemption." From a medical perspective, these two terms are vastly different and cause uncertainty as to what Mrs. Fulop is required to show in order to establish that the child medically cannot receive the vaccination. *See, Exhibit C, Hearing Transcript, pp 146-148* (discussing Petitioner-Appellee's definition of a "medical exemption" to the MMR vaccine). These ambiguous and conflicting statements confuse the standard and deprived Mrs. Fulop of mounting a viable defense to the Summons. Furthermore, Mrs. Fulop was clearly not provided "an accurate statement of the matter to be adjudicated" as required by NYCC § 1046.

In sum, the Commissioner's Order and the Board's Resolution are a total imbroglio. The Summons does not provide an accurate statement of the matter to be adjudicated and does not provide a layperson with reasonable notice of which order was violated. Therefore, it was an error of law for the Hearing Officer to sustain the Summons because Petitioner-Appellee failed to provide Mrs. Fulop an accurate statement of the matters to be adjudicated as required by the New York City Charter § 1046 and fair notice as required by due process of law, and thus the Tribunal must dismiss the Summons.

IV. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FULOP OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW CROSS-EXAMINATION OF THE ISSUING OFFICER WHERE A DISPUTE OF FACT WAS PRESENTED

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Fulop of a full and fair hearing by refusing to allow cross-examination of the issuing officer where a dispute of fact was presented.

"A respondent may request the [issuing officer's] appearance if it makes an offer of proof to refute the allegations on a summons and it persuades the Hearing Officer that cross-examining the [issuing officer] about a disputed fact would be helpful." *NYC v. Vantage Associates, Inc.* (Appeal No. 1100746, October 27, 2011). Counsel for Mrs. Fulop proffered that cross-examination of the issuing officer was necessary in order to establish whether the MMR vaccine was medically appropriate for the child and whether proof of a medical exemption was requested before the Summons was issued. The Hearing Officer declined Mrs. Fulop's application to cross-examine the issuing officer, holding that the doctor appearing on behalf of the Petitioner-Appellee, Dr. Jennifer Rosen ("Dr. Rosen"), was available and could answer any questions regarding these disputed facts. **Exhibit C, Hearing Transcript, p 14.** However, when questioned, Dr. Rosen lacked any knowledge of the facts leading to the issuance of the Summons and was unable to

present any responses to questions directed at these disputed facts. For example, Dr. Rosen: did not know where the child was exposed (**Exhibit C, Hearing Transcript, p 107**); did not know where the child's address was obtained (**Exhibit C, Hearing Transcript, p 109**); did not know if the child had any medical contraindication to MMR before the Summons was issued (**Hearing Transcript, p 117**); and did not know if any person from the health department had contacted Mrs. Fulop to determine if the child had been given MMR before the Summons was issued (**Hearing Transcript, p 117-118**).⁸

Thus, it was an error of law for the Hearing Officer to refuse Mrs. Fulop the ability to cross-examine the issuing officer and deprive Mrs. Fulop of a full and fair hearing, and the Tribunal must dismiss the Summons.

V. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER DEPRIVED MRS. FULOP OF A FULL AND FAIR HEARING BY REFUSING TO ALLOW A REASONABLE CROSS-EXAMINATION OF PETITIONER-APPELLEE'S EXPERT

The Tribunal should dismiss the Summons because it was an error of law for the Hearing Officer to deprive Mrs. Fulop of a full and fair hearing by refusing to allow a reasonable cross-examination of Petitioner-Appellee's expert, Dr. Rosen.

The Hearing Officer refused to allow Mrs. Fulop's counsel an opportunity to conduct a reasonable cross-examination of Dr. Rosen. **Exhibit C, Hearing Transcript, pp 131-133; 240**. In fact, most of the hearing time was devoted to the Hearing Officer unreasonably curtailing the cross-examination of Dr. Rosen and Dr. Rosen refusing to provide responsive answers to questions. **Exhibit C, Hearing Transcript, pp 152-153**. Therefore, the Hearing Officer

⁸ This line of questioning was regarding the child associated with Summons Number 30198-19L0. However, in the interest of judicial economy, the parties and the Hearing Officer agreed to incorporate the arguments and exhibits from the hearing on Summons Number 30198-19L0 into the record for Mrs. Fulop's hearing. **Exhibit C, Hearing Transcript, pp 142-143; 241-242**.

committed an error of law by preventing Mrs. Fulop's counsel of the chance to reasonably cross-examine Dr. Rosen and deprived Mrs. Fulop of a full and fair hearing, and as such the Tribunal must dismiss the Summons.

VI. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE HEARING OFFICER'S DECISION LACKED A RATIONAL BASIS AND IS NOT FACTUALLY SUPPORTED

The Tribunal should dismiss the Summons because the Hearing Officer's decision lacked a rational basis and is not factually supported.

The Hearing Officer stated in his written decision that Mrs. Fulop "*relied upon* the last paragraph of the Order, which states, '[t]his Order shall remain in effect until the next meeting of the NYC Board of Health scheduled for April 17, 2019, at which time it may be continued or rescinded by the Board'" to make the argument that the Order expired on April 17, 2019. **Exhibit B, Hearing Decision.** (emphasis added.) However, Mrs. Fulop did not *rely upon* this statement made in the Commissioner's Order. Instead, Mrs. Fulop's argument was firmly grounded in NY City Health Code (24 RCNY) § 3.01 (d) and was merely reinforced by the language stated in the Commissioner's Order. In fact, counsel for Mrs. Fulop read the charter provision on the record in support of this argument. **Exhibit C, Hearing Transcript, pp 26-29.** Counsel for Mrs. Fulop paused during this argument because it appeared as though the Hearing Officer was not paying attention. **Exhibit C, Hearing Transcript, p 29.** Thus, the Hearing Officer failed to consider applicable law.

Moreover, counsel for Mrs. Fulop made an extensive argument that upholding the violation as to the child was unjust, entered 45 documents into evidence to support the conclusion, and cited to and read into the record the Hearing Officer's authority to dismiss a summons based upon the interest of fairness and justice found at NYCC § 1049 (5) (a). **Exhibit C, Hearing Transcript, p**

151 p 172; p183. Petitioner-Appellee presented no counter-argument regarding this issue. The New York City Charter § 1049 requires the Hearing Officer to consider nine factors when reaching a determination on issues of fairness and justice; yet, the Hearing Officer failed to address any of these factors or reach a determination on this issue in his written decision.

Furthermore, counsel for Mrs. Fulop made an extensive argument that the MMR vaccine was medically inappropriate as to the child and entered 550 pages of documents to support this conclusion. **Exhibit C, Hearing Transcript, pp 138-139; p 172; p183.** The Hearing Officer failed to address this issue or reach a determination in his written decision, even though the Summons states “medically appropriate” as a reason to forgo MMR vaccination. The Exhibits presented are summarized in Section X below.

Finally, the Hearing Officer held in his written decision that the “April 17, 2019 Resolution continued the Commissioner’s exercise of emergency authority, which operated to continue the validity of the Commissioner’s April 9, 2019 Order.” **Exhibit B, Hearing Decision.** This finding is not supported by the facts because both parties agreed on the record that the Commissioner’s Order expired on April 17, 2019. **Exhibit C, Hearing Transcript, p. 58.** The Commissioner’s Order cannot simultaneously expire and continue to be valid. In the alternative, the Hearing Officer’s finding that the Commissioner’s “exercise of authority” was continued by the Resolution is not dispositive of the issues presented at the hearing because the Summons cites Mrs. Fulop as having violated the Commissioner’s written order, not the Commissioner’s exercise of emergency authority. Therefore, the Hearing Officer’s finding that the Board continued the Commissioner’s exercise of authority is irrelevant.

Consequently, the Hearing Officer failed to consider the applicable law and argument when making his decision. For these reasons, the Hearing Officer’s decision lacked a rational basis and

is not factually supported; hence, Mrs. Fulop was deprived of a full and fair hearing, and the Tribunal must dismiss the Summons.

VII. THE SUMMONS SHOULD BE DISMISSED BECAUSE IT WAS ARBITRARY AND CAPRICIOUS FOR THE HEARING OFFICER TO SUSTAIN A SUMMONS MANDATING A VACCINATION FOR A CHILD UNDER TWELVE MONTHS OLD WHERE THE FOOD AND DRUG ADMINISTRATION HAS NOT LICENSED THAT VACCINATION FOR CHILDREN UNDER TWELVE MONTHS OLD

The Tribunal should dismiss the Summons because it was arbitrary and capricious for the Hearing Officer to sustain the Summons mandating the MMR vaccine for a child less than twelve months old. On the date of occurrence, the child was less than twelve months old. **Respondent-Appellant's Hearing Exhibit 98, Declaration of Chanic Fulop, Child's Date of Birth.** The Food and Drug Administration ("FDA") has not licensed MMR for children less than twelve months old. Mrs. Fulop presented undisputed evidence at the hearing that the MMR vaccine is not licensed for this age group and that the "safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established." **Respondent-Appellant's Hearing Exhibit 30.** Therefore, the Summons and the Hearing Officer's order are both saying that Mrs. Fulop's child must receive a vaccination even though the FDA has not determined that it is safe and effective for the child. This is patently arbitrary and capricious because there is no reasonable basis for the Hearing Officer to uphold a violation for failure to vaccinate a child with MMR where the vaccine is not licensed for use in the child.

VIII. THE SUMMONS SHOULD BE DISMISSED PURSUANT TO NYCC § 1049 (5) (a)

The Summons should have been dismissed pursuant to NYCC § 1049 (5) (a) because the undisputed evidence at the hearing reflected the following:

Exhibit 2 – CDC, *MMR Vaccine Information Statement* (listing some of the side effects of the MMR vaccine, including seizure, full-body rash, deafness, long-term seizures, coma, lowered consciousness, and brain damage).

Exhibit 3 – FDA, *Summary of Clinical Investigation Studies of [MMR] for Purposes of Support for License* (reflecting that only around 800 children participated in the underpowered pre-licensing study, no-placebo control group, and a safety review period of a mere 42 days).

Exhibit 4 – FDA, *ibid* (summarizing the 215-pages of Exhibit 3 and including charts that show the high rate of upper respiratory infection and gastrointestinal illnesses for trial participants).

Exhibit 5 - Institute of Medicine (“IOM”), *Adverse Effects of Pertussis and Rubella Vaccines* (demonstrating that the available science supports a causal relationship between the rubella vaccine and chronic and acute arthritis).

Exhibit 6 - IOM, *Adverse Events Associated with Childhood Vaccines* (revealing that for 18 of the 22 most reported adverse events following MMR in 1994, the CDC had not conducted the science to determine if the MMR was causally linked to the adverse events; however, the available science did show that MMR was causally linked to anaphylaxis, thrombocytopenia, and death).

Exhibit 7 - IOM, *Adverse Effects of Vaccines, Evidence and Causality* (showing that in 2012, the CDC had not conducted the science to determine if 23 of the 31 commonly claimed injuries from the MMR vaccine were causally linked to the vaccine).

Exhibit 8 - IOM, *Adverse Events Associated with Childhood Vaccines* (finding scant science researching why some people react negatively to vaccines and encouraging CDC to conduct the science).

Exhibit 9 – IOM, *Adverse Effects of Vaccines, Evidence and Causality* (stating that the CDC still has not conducted the science to determine which children may be injured by vaccination).

Exhibit 10 - Nature Genetics, *Common variants associated with general and MMR vaccine-related febrile seizures* (identifying specific genetic markers for when a child will have seizures after MMR vaccination).

Exhibit 11 – *\$101 Million Award for Encephalopathy from MMR Vaccine* (reporting payment of \$101 million to parents of a child injured by the MMR vaccine).

Exhibit 12 – CDC, *Vaccine Excipient & Media Summary* (listing the excipient and media contained in the MMR vaccine, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin).

Exhibit 13 - ATTC, *MRC-5* (showing that the MRC-5 cell line is derived from the lung tissue of a 14-week-old male fetus).

Exhibit 14 - ATTC, *WI-38* (describing that the WI-38 cell line was derived a 3-month-old female fetus).

Exhibit 15 - The National Catholic Bioethics Quarterly, *A Brief History of Human Diploid Cell Strains* (describing how dozens of fetuses were used to develop fetal cell lines for use in vaccines).

Exhibit 16 - Proceedings of the Society of Experimental Biology and Medicine, *Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses* (revealing that 80 aborted fetuses were used to create the rubella component of the MMR vaccine).

Exhibit 17 - Sound Choice Pharmaceutical Institute, *Open Letter to Legislators Regarding Fetal Cell DNA in Vaccines* (discussing fetal DNA contaminants in the MMR vaccine).

Exhibit 18 - Atherosclerosis, *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study* (finding that measles and/or mumps infection was associated with significantly lower risks of mortality from cardiovascular disease).

Exhibit 19 - CDC, *Heart Disease Facts & Statistics* (indicating that 610,000 people die of heart disease in the United States every year).

Exhibit 20 - Leukemia Research, *Do childhood diseases affect NHL and HL risk? A case-control study from northern and southern Italy* (finding that participants who did not have a history of measles infection had a 66 percent increased rate of Non-Hodgkin's Lymphoma and 233 percent increase of Hodgkin's Lymphoma).

Exhibit 21 - Medical Hypotheses, *Febrile history infectious of cancer childhood diseases in the patients and matched controls* (finding a history of febrile infectious childhood disease, such as measles, lowers the risk for cancer).

Exhibit 22 - British Medical Journal, *Infantile Hodgkin's Disease: Remission after Measles* (describing remission of cancer after a measles infection).

Exhibit 23 - NIH, *Cancer Stat Facts: Non-Hodgkin Lymphoma* (reporting 74,200 new cases of Non-Hodgkin Lymphoma in 2019).

Exhibit 24 - NIH, *Cancer Stat Facts: Hodgkin Lymphoma* (indicating 8,110 new cases of Hodgkin Lymphoma in 2019).

Exhibit 25 – Cancer Detection and Prevention, *Acute infections as a means of cancer prevention: Opposing effects to chronic infections?* (finding that exposures to febrile infectious childhood diseases, including measles, were associated with subsequently reduced risks for melanoma, ovary, and multiple cancers combined).

Exhibit 26 – NIH, *Cancer Stat Facts: Ovarian Cancer* (reporting 22,530 new cases of ovarian cancer in 2019).

Exhibit 27 – Pediatrics, *Allergic Disease and Atopic Sensitization in Children in Relation to Measles Vaccination and Measles Infection* (finding that measles infection may protect against allergic disease in children).

Exhibit 28 – Allergol et Immunopathol, *Frequency of allergic diseases following measles* (finding that allergic diseases are less frequent in children with a history of measles).

Exhibit 29 – American Journal of Epidemiology, *Measles Infection and Parkinson's Disease* (finding a statistically significant reduced risk of Parkinson's disease for those who had measles during childhood).

Exhibit 30 – Merck, *MMR Manufacturers' Package Insert* ("M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility").

Exhibit 31 – PloS One, *Adverse Events following 12 and 18 Month Vaccinations: a Population-Based, Self-Controlled Case Series Analysis* (finding significantly elevated risks of emergency room visits one to two weeks following 12 and 18-month MMR vaccination).

Exhibit 32 – FDA, *Supplemental Approval Letter for MMR* (adding to the Adverse Reactions section of the MMR package insert "transverse myelitis" in 2014 and "Henoch-Schonlein purpua" and "acute hemorrhagic edema of infancy" in 2017).

Exhibit 33 – Journal of Translational Science, *Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children* (finding that vaccinated individuals had a higher rate of several forms of chronic illness and neurodevelopmental disorders).

Exhibit 34 – U.S. House of Representatives, Committee on Government Reform, *Conflicts of Interest in Vaccine Policy Making*, June 15, 2000 (discussing the conflicts of interest that vaccine policy-makers have with pharmaceutical companies).

Exhibit 35 – CDC, *Notice to Readers: Recommended Childhood Immunization Schedule -- United States, 2000* (reflecting that the MMR vaccine was on the childhood immunization schedule when the Committee on Government Reform issued its Majority Staff Report regarding conflicts of interest in June 2000).

Exhibit 36 – 42 USC 300aa-27, *Mandate for safer childhood vaccines* (statutory section underpinning vaccine safety in this country which required the United States Department of Health and Human Services (“HHS”) to submit a biennial report to Congress detailing improvements made regarding vaccine safety).

Exhibit 37 – *Informed Consent Action Network v. HHS*, 18-cv-03215, Stipulation & Order, dated July 6, 2018 (evidencing that HHS has never once submitted a report to congress as required by 42 USC 300aa-27).

Exhibit 38 – HHS, Response to Freedom of Information Act Request (admitting that the Task Force for Safer Childhood Vaccines required by 42 USC 300aa-27 was disbanded in 1998).

Exhibit 39 - Physicians for Informed Consent, *Measles What Parents Need to Know* (detailing the benefits and risks of the MMR vaccine).

Exhibit 40 – Archives of Pediatrics & Adolescent Medicine, *Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment* (finding that measles antibodies wane over time in the absence of circulating wild-type measles).

Exhibit 41 – The Lancet, *Measles Virus Infection Without Rash In Childhood Is Related To Disease In Adult Life* (evidencing association between a negative history of measles and development of immunoreactive diseases, sebaceous skin diseases, degenerative diseases of bone and cartilage, and certain tumors).

Exhibit 42 – CDC, Vaccine Adverse Event Reporting System (VAERS) Results (results of the number of individuals receiving a measles-containing vaccine in 2013 that required a hospital, medical office, or emergency room visit after vaccination).

Exhibit 43 – CDC, *Vital Statistics of the United States 1940-1960* (showing that the death rate from measles in the United States declined by over 98 percent between 1900 and 1962).

Exhibit 44 – Brain & Development, *Spontaneous improvement of intractable epileptic seizures following acute viral infections* (showing that seizures disappeared within two weeks after viral infections such as measles).

When provided an opportunity to rebut any of the foregoing evidence, the Petitioner declined to proffer any evidence in rebuttal.

Thus, the undisputed evidence reflects that the MMR vaccine for the child was not medically appropriate, as the risks of injecting this product into the child outweigh the benefits.

IX. THE SUMMONS SHOULD BE DISMISSED BECAUSE THE COMMISSIONER AND BOARD'S ACTIONS VIOLATE THE STATE AND UNITED STATES CONSTITUTIONS

The Tribunal should dismiss the Summons because the Commissioner's Order and Resolution violate New York and United States Constitutions. Although this tribunal is unable to rule on issues of Constitutional law,⁹ Mrs. Fulop reserves all issues and all Constitutional claims for appeal, including but not limited to, the following:

1. First Amendment, Free Exercise of Religion;
2. Fourteenth Amendment, Substantive Due Process and Equal Protection;
3. Fourth Amendment, Unlawful Search and Seizure;
4. Fifth Amendment, Procedural Due Process;
5. Eighth Amendment, Cruel and Unusual Punishment;
6. Ninth Amendment; and
7. Other Unenumerated Rights.

DEMAND FOR RELIEF

The Tribunal should reverse the Hearing Officer's decision to sustain the Summons for the reasons stated above.

⁹ "Respondent's Constitutional claims under the First Amendment, the Commerce Clause, substantive Due Process, and State and Federal privacy rights are not properly adjudicated by this Tribunal." *TLC v. Fortune Limousines, Inc.*, Appeal No. JRB000737 (March 6, 2019) (citing *DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Dated: November 30, 2019

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DOHMH v. Chanie Fulop
30328-19L0

I. The hearing officer did not err in finding that the Commissioner's Order did not expire on April 17, 2019 and Respondent was in violation

The hearing officer was correct in finding that the New York City's Department of Health ("Department") Commissioner's Order dated April 9, 2019 (Commissioner's Order") and was continued by the Board of Health's Resolution dated April 17, 2019 ("Resolution") *See DOHMH v. J.DOE.*, Appeal No. 30329-19L0 (December 20, 2019) (finding that Board of Health Continued Emergency Order). Additionally, both the Resolution and the Commissioner's Order are referenced in the Summons No. 30328-19L0's ("Summons") violation description as the requirements violated by Respondent and therefore both are applicable in determining the violation.

Pursuant to Health Code section 3.01(d) the Commissioner may declare a public health emergency and issue orders that "shall be effective only until" the meeting of the Board, whereupon "the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power." Contrary to what Respondent asserts, Health Code section 3.01(d) does not limit the Board to, as Respondent states, "only allow[ing] the Board to continue the order 'as is' ..." (Appeal page 4). Respondent would like to add onto Health Code section 3.01(d) a limitation of the powers of the Board of Health to continuing orders only 'as is', 'expiring' or needing to 'issue a new order' but these limits are not in the plain language of the section.

It is apparent in reading the Resolution that it continues the Commissioner's exercise of power asserted in her Order since the Resolution repeats the main directive of the Commissioner's Order, which is that people living in the 11205, 11206, 11211 and 11249 zip codes who have not been vaccinated against measles shall be vaccinated against measles unless they can demonstrate immunity or a medical exemption. The Resolution also reiterates the main findings of the Commissioner's Order such as the declaration of a measles outbreak in the Williamsburg area, the threat of measles to public health in the City of New York and the need to vaccinate to control the outbreak. *See e.g.* Commissioner's Order (8th paragraph)("Whereas, I find the ongoing outbreak in Williamsburg to be an existing threat to public health in the City of New York; and.."); *c.f.* Resolution (15th paragraph)("Resolved, that the Board of Health hereby declares that an outbreak of measles is ongoing in the neighborhood of Williamsburg...").

Respondent incorrectly asserts (Appeal page 4) that Petitioner conceded on page 58 of the hearing transcript that the Commissioner's Order expired on April 17, 2019. The Department's General Counsel made no such admission. While it is true, as Respondent points out, that there are a few differences in language used in the orders, the differences amount to semantics and do not affect the applicability of the Commissioner's Order or the Resolution to the Summons or Respondent's violation. Whether the language of the Commissioner's Order or the language of

the Resolution is applied to the Summons, the Respondent will still be found in violation since Respondent's child lived and resided in the applicable zip code, lacked immunity and did not have a valid medical exemption, which indicates in operation the Resolution continues the Commissioner's Order.

Accordingly, the decision should be affirmed.

II. Respondent was properly served the Summons

The hearing officer was correct in concluding that Respondent was provided proper service as was evidenced in the submitted certificate of service that stated the Summons was mailed. Improper mailing is not proven simply by a declaration of Respondent she did not receive the mailing. *See DOHMH v. Joan Moriello*, Appeal No. 1801264 (December 12, 2018) ("Her mere denial that she received the mailing is inadequate to overcome the presumption that properly addressed mail is received, absent any evidence or testimony demonstrating the mailing would be unlikely to arrive.") (*citing DOB v. Banyer Place Development LLC*, Appeal No. 1800075 (April 5, 2018)).

Accordingly, the decision should be affirmed.

III. The Summons provided reasonable notice to Respondent to satisfy due process

The standard for the contents of a Summons is provided in Title 48 of the Rules of the City of New York sections 6-08(c)(2) and (3), which states, in relevant part, that a "summons must contain, at a minimum: ... (2) A clear and concise statement sufficient to inform the Respondent with reasonable certainty and clarity of the essential facts alleged to constitute the violation or the violations charged; (3) Information adequate to provide specific notification of the section or sections of the law, rule or regulation alleged to have been violated...". Here, petitioner clearly met the burden of adequate notice because the Summons states the essential facts to constitute the violation: the date the records of the child were reviewed, that upon that date the Respondent's child was found not to be vaccinated against measles, have immunity or a medical exemption. The Summons also provides adequate notice of the orders alleged to be violated as the Summons states the requirements of both the Commissioner's Order and Resolution.

The discrepancies pointed out by Respondent between the Resolution and the Commissioner's Order do not prejudice Respondent as none of the differences have prevented the Respondent from knowing the elements of the violation or being able to put on a defense to the allegations. *See TLC v. Shaikh Ali*, Appeal No. 10105610C (April 5, 2019) ("The identity of the vehicle is not an element of the charge and is therefore irrelevant to whether or not Respondent received adequate notice."). In the absence of any demonstrated prejudice, dismissal based on notice is not warranted. *See TLC v. Tawfik Al Shammaa*, Appeal No. 72140348A (November 13, 2017). Respondent plainly had notice of the elements of the charge as Respondent presented a full lengthy defense by presenting 44 exhibits concerning the measles vaccination and its medical appropriateness in response to the orders vaccination requirements. *See TLC v. Ibrahima Fall*,

Appeals No. 10087317C (March 12, 2018) (“Finally, the respondent prepared for the hearing by taking a video of the traffic lights along the route, showing, together with his testimony he clearly remembered the incident, that he was sufficiently notified of and understood the charge against him.”).

Accordingly, the decision should be affirmed.

IV. The hearing officer did not deprive the Respondent a full and fair hearing by declining to Order that the issuing officer testify

There is no requirement for an OATH hearing officer to grant a request for the issuing officer to testify. According to Title 48 of the Rules of the City of New York Chapter 6-15, “Upon request of either party, a Hearing Officer may grant an adjournment for the testimony of an Inspector if the Hearing Officer finds that the Inspector’s testimony is likely to be necessary to a fair hearing on the violation(s) charged and/or the defense(s) asserted.” The hearing officer clearly has the authority to use discretion to determine whether to grant a request for the issuing officer to testify.

Additionally, it is well established that there is no absolute right to cross examine a witness in an administrative hearing. *See Gordon v. Brown*, 84 NY2d 574 (1994).

In this case, the hearing officer heard arguments by the petitioner and respondent as to whether the issuing officer should be required to testify and properly used his discretion to determine that issuing officer was not required to testify for the respondent to receive a fair hearing. The testimony of Dr. Rosen, a physician with the NYC Department of Health, was enough to ensure the respondent received a fair hearing.

Accordingly, the decision should be affirmed.

V. The hearing officer did not deprive the Respondent a fair hearing by refusing to allow a reasonable cross-examination of Dr. Rosen

Counsel for the respondent was given a full opportunity to cross examine Dr. Rosen about the allegations in the summons. In fact, the respondent has failed to produce any evidence that counsel for the respondent was prevented from asking questions directly related to the allegations. To the contrary, the hearing officer permitted the hearing to go on for hours adjudicating and covered topics well beyond the scope of the summons. Clearly, counsel for the respondent was able to inquire and receive responses on all questions relevant to the allegations. The hearing officer acted appropriately and fairly throughout the hearing.

Accordingly, the decision should be affirmed.

VI. The Summons should not be dismissed because Respondent alleges the hearing officer’s decision lacked a rational basis and is not factually supported

Title 48 of the Rules of the City of New York Chapter 6-19(g)(1) provides that “the Appeals Unit within the Tribunal will determine whether the facts contained in the findings of the Hearing Officer are supported by a preponderance of the evidence in the record, and whether the determinations of the Hearing Officer, as well as the penalties imposed, are supported by law.”

The hearing officer decision is based on the preponderance of the evidence and testimony provided as he cites to the arguments and evidence presented by each side. The issue here is that Respondent disagrees with the hearing officer’s findings, however, that is not grounds to reverse the decision. It has been held that “[w]here evidence conflicts and a Hearing Officer’s decision is based on the credibility of the evidence presented, the Hearing Officer’s decision will be upheld since he or she observed the demeanor of the witnesses and weighed the evidence presented in the first instance.” *TLC v. Irshan Mohamed Sufiyan Mohamed*, Appeal No.10112809C (November 15, 2019), citing *Berenhaus v. Ward*, 70 NY2d 436 (1987); *Matter of Ifrah v. Utschig*, 98 NY2d 304 (2002).

Accordingly, the decision should be affirmed.

VII. The Summons should not be dismissed because Respondent alleges it is arbitrary and capricious for the hearing officer to sustain the Summons

Respondent provides no basis for their constitutional argument that this Tribunal cannot sustain a summons that requires a child under twelve months be vaccinated since the decision is arbitrary and capricious and lacks rational basis. We agree with Respondent that constitutional arguments are beyond the scope of the Tribunal (Appeal page 19, footnote 9) but the Summons does not require constitutional conclusions to be decided.

The violation in the Summons is within the jurisdiction of the Tribunal as provided in Title 48, § 6-02, which states that “the Tribunal has jurisdiction to hear and determine summonses alleging non-compliance with the provisions of the Health ... relating to or affecting health within the City and any other laws or regulations that the Department of Health and Mental Hygiene has the duty or authority to enforce.”

Accordingly, the decision should be affirmed.

VIII. The Summons cannot be dismissed pursuant to New York City Charter Section 1049(5)(a)

The ability for a hearing officer to dismiss a summons in the interest of justice pursuant to Charter section 1049(5) is limited to specified violations listed in Charter section 1049(4)(b). Charter §1049(5)(“...an administrative law judge or hearing officer may dismiss a notice of violation *for a specified violation, as defined by paragraph (b) of subdivision 4 of this section*, when dismissal is appropriate in the interest of justice, *within the meaning of this subdivision*”)(emphasis added).

The specified violations stated in Charter section 1049(4)(b) do not include the violation of Health Code section 3.05 at issue here. Therefore, Charter section 1049(5)(a) is not applicable

and cannot be used to dismiss the summons. Further, even if Charter section 1049(5)(a) was applicable, the summons cannot not be dismissed on such basis, as none of the compelling factors, considerations, or circumstances enumerated in Charter section 1049(5)(a) were presented at the hearing or in Respondent's appeal.

Accordingly, the decision should be affirmed.

IX. The Summons should not be dismissed because of any alleged violations of State and United States Constitutions

As mentioned above, Respondent concedes in their appeal (page 19, footnote 7) that Respondent's Constitutional claims cannot be properly adjudicated by this Tribunal. *See, e.g., DCA v. EMS Pregnancy Center*, Appeal No. 170095HR (June 29, 2018) (finding that the Tribunal was not the proper forum for adjudicating First Amendment claims as a defense to a statutory disclosure scheme); *NYC v. Aihua Gong*, Appeal Nos. 1601234-41 (January 5, 2017) (finding that the Tribunal is not the proper forum to adjudicate a claim of Constitutional right to privacy); *DCA v. Mr. C's Cycles*, Appeal No. 05390932 (February 28, 2017) (finding that the Tribunal is not the proper forum to adjudicate a Commerce Clause challenge).

Accordingly, the decision should be affirmed.



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Hearings Division

9 Bond Street, 7th Floor
Brooklyn, NY 11201

APPEALS DECISION

<p>DEPARTMENT OF HEALTH & MENTAL HYGIENE, -against-</p> <p>CHANIE FULOP 115 WALLABOUT STREET BROOKLYN, NY 11206</p> <p>(Respondent)</p>	<p>Violation/Summons No.: <u>30328-19L0</u></p> <p>Decision Date: <u>5/5/2020</u></p> <p>Hearing Officer: <u>Zeitler Richard</u></p> <p>Respondent's Rep.: <u>Aaron Siri, Esq.</u></p> <p>Petitioner's Rep.: <u>Thomas Merrill, Esq., Loraine Peone, Esq. and Dr. Jennifer Rosen, MD</u></p> <p>Type of Hearing: <u>Appeal</u></p>
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Summary Disposition: AFFA

LINE ITEM	VIOL. CODE	CONDITION (SEVERITY)	CODE SECTION	FINDINGS	DECISION CODE	PENALTY
1	N	N	3.05		Sustained	\$0.00
					TOTAL:	\$0.00



OFFICE OF ADMINISTRATIVE TRIALS AND HEARINGS
Appeals Unit

66 John St., 10th Floor
 New York, NY 10038
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Appeal No. 30328-19L0

DOHMH v. J. Doe¹

April 24, 2020

APPEAL DECISION

The appeal of Respondent, parent of a child who is at least six months of age, is **denied**.

Respondent appeals from a hearing decision by Hearing Officer D. Leung (Brooklyn), dated September 25, 2019, sustaining one violation of the New York City Health Code (HC) § 3.05 for failing to comply with an order of the Commissioner of Health to have an infant vaccinated against measles.² Having fully reviewed the record, the Tribunal finds that the hearing officer's decision is supported by the law and a preponderance of the evidence. Therefore, the Tribunal finds as follows:

Summons	Law Charged	Hearing Determination	Appeal Determination	Penalty
30328-19L0	HC § 3.05	In Violation	Affirmed – In Violation	\$1,000

BACKGROUND

In the summons, on May 23, 2019, the issuing officer (IO) affirmed reviewing the records of Petitioner, the Department of Health and Mental Hygiene (DOHMH), on May 22, 2019, and observing that Petitioner's Citywide Immunization Registry (CIR), which collects immunization records for all children receiving vaccines in New York City and which is required to be updated by medical providers, had no record of measles immunization for Respondent's child, who was at least six months old and resided at a stated address in Brooklyn. The summons alleged that Respondent's failure to vaccinate the child was in violation of a Commissioner's Order, which was issued on April 9, 2019, pursuant to Article 3 of the HC, in response to a public health emergency, and which ordered that all persons who live, work or attend school within certain specified ZIP codes in Brooklyn be vaccinated against measles within forty-eight hours of the Order. The summons stated that the Order was to remain in effect until the next meeting of the New York City Board of Health (BOH) scheduled for April 17, 2019, "at which time it may be continued or rescinded by the Board." The summons further alleged that on April 17, 2019, the BOH approved a resolution (Resolution) continuing the public health emergency and vaccination requirement and providing that the parent and/or guardian of a child who is not vaccinated be fined unless they demonstrate proof of immunity or that immunization is not medically appropriate.

At the hearing, held on September 25, 2019, Respondent was represented by her attorney. Petitioner was represented by its general counsel, another DOHMH attorney, and a DOHMH physician. The IO did not appear.³ Petitioner relied on the summons and the DOHMH physician's testimony and knowledge of its records. The parties agreed that the arguments made and evidence submitted in the hearing previously held for Docket No. 30198-19L0 were to be incorporated in this hearing, including the Commissioner's Order

¹ J. Doe is used here to protect the privacy of Respondent's child.

² The Health Code is found in Title 24 of the Rules of the City of New York (RCNY).

³ Respondent did not waive the appearance of the IO. The hearing officer ruled that the IO was not required for Respondent to get a fair and impartial hearing.

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and the BOH Resolution. Respondent did not deny the essential facts of the summons, specifically that an emergency Order to vaccinate was issued, that the subject child lived in one of the targeted ZIP codes,⁴ and that the child was not vaccinated. In the prior hearing, Respondent argued that the Order had already expired on the date of the summons and Respondent could not be charged with violating an expired Order. Respondent argued that because the BOH Resolution had terms that differed from the Order,⁵ and because the Resolution did not specifically state that it was continuing the expiring Order, the Order was not continued. Respondent further argued that although Petitioner could have charged a violation of the BOH Resolution, in fact the charging language was only for the Order. In addition, Respondent argued that Petitioner did not establish that it was medically appropriate for the subject child to be vaccinated. Documents previously offered by Respondent regarding the efficacy and safety of the vaccination in general were also incorporated in this record. In this hearing, and in several earlier hearings, Respondent asserted that the vaccine was not licensed for children under one year of age, and in this hearing noted that although Petitioner follows a recommendation that the vaccine be given during a measles outbreak, such use is not mandated. Respondent submitted the parent's declaration of a religious objection to the vaccine.⁶ In addition, Respondent submitted a notarized statement that she did not receive the summons in the mail although she admitted that it was posted on the door. These declarations were taken into evidence without objection.

Petitioner's arguments, incorporated from the prior hearing, were that HC § 3.01(b) gave the Commissioner of Health authority in an emergency to exercise the BOH's power to issue an order, which would be effective until the next BOH meeting, and that the BOH continued the Order in its Resolution by continuing the finding of emergency and the requirement to vaccinate. Petitioner argued that Respondent was also in violation of the Resolution, which itself constituted an order under HC § 3.05, and for which notice was provided in the narrative of the summons; and that the Resolution was by its terms effective immediately, that is, on the date of issuance.⁷ Petitioner's previous submissions, incorporated here, included "Frequently Asked Questions" regarding the measles vaccine, published along with the Order, and a copy of the decision in *C.F. v. The New York City Department of Health and Mental Hygiene*,⁸ denying injunctive relief from the Order, claimed on scientific, religious, and moral grounds. The DOHMH doctor testified that the Advisory Committee on Immunization Practices,⁹ which sets the national standards for vaccination, recommends that the vaccine be given to children age six to twelve months in an outbreak setting and routinely prior to international travel. As to the argument for a religious exemption, Petitioner noted that a religious objection was not a defense

⁴ In the hearing for Docket No. 30198-19L0, the DOHMH physician testified that addresses were provided by several sources, including health care facilities, but was not able to say which source provided the address of the subject child. Respondent, however, did not assert that the subject child did not live within the affected ZIP codes.

⁵ Respondent noted such differences as follows: Where the Order included people who resided in the affected area and who were over six months of age, the Resolution omitted residents and included children who were six months of age; where the Order declared the people who had not received the MMR vaccination to be the nuisance, the Resolution declared the outbreak of measles to be the public nuisance; where the Order did not apply to schools, preschools or child care services, the Resolution included those attending school, preschool or child care; and where the Order encompassed criminal fines, forfeiture, and imprisonment as punishments, the Resolution did not.

⁶ Respondent asserted that her religion did not permit putting foreign substances into the body and, in addition, that this vaccine derived from a non-kosher species.

⁷ As this summons was written after the Resolution's three-day publication period, Respondent did not pursue its earlier argument challenging a summons that was issued during the publication period.

⁸ See 2019 NY Slip Op 31047 (April 18, 2019).

⁹ As noted in an earlier hearing, the DOHMH doctor was referring to a committee of the Centers for Disease Control and Prevention (CDC).

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to the Order, and as to service of the summons, Petitioner provided a copy of the deputy sheriff's affidavit of mailing.

In the decision, the hearing officer reviewed the arguments of the parties and found that the BOH, by its April 17, 2019, Resolution continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's Order of April 9, 2019. He noted the record made and evidence previously submitted on Constitutional and scientific arguments and found that they were beyond the scope of the hearing. He noted and credited the testimony of the DOHMH physician that in emergency/outbreak situations, an MMR vaccine is appropriate for a child between six and twelve months.¹⁰ He credited Petitioner's certificate of service and found that the summons was properly mailed to Respondent's address. In addition, he found that a religious objection was not a valid defense to the charge. The hearing officer found that the allegations in the summons supported a violation of the cited section of law and that Respondent's evidence did not provide a defense to the allegations.

On appeal, Respondent repeats by incorporation the arguments raised in Docket No. 30198-19L0 relevant to this and other cases regarding compliance with the emergency Order to vaccinate against measles.¹¹ Respondent argues that she did not have a full and fair hearing because she could not cross-examine the IO to establish whether the MMR vaccine was medically appropriate for the child and because the hearing officer did not allow a reasonable cross-examination of Petitioner's expert. Respondent argues that the summons should be dismissed because the hearing officer's decision lacked a rational basis; in the interests of justice pursuant to New York City Charter (NYCC) § 1049, found in Chapter 45-A; and on New York State and United States Constitutional grounds, which include religious objections.

Petitioner repeats the arguments incorporated from the hearing in Docket No. 30198-19L0. Petitioner asserts that the hearing officer was correct that the Order of April 9, 2019, was continued by the BOH Resolution, citing the Tribunal's decision in *DOHMH v. J. Doe*, Appeal No. 30329-19L0 (December 20, 2019). Petitioner argues that HC § 3.01(d) allows the BOH to continue the Order as is, but does not limit BOH action to continuing or rescinding the Order. Petitioner repeats the argument that the Resolution continued the Commissioner's exercise of power, as it repeats the Order's main directive, that people living in the specified ZIP codes be vaccinated unless they can demonstrate immunity or a medical exemption. Petitioner asserts that Respondent was in violation whether the language of the Order or the language of the Resolution is applied. Petitioner argues that the summons provided adequate notice of the charges pursuant to §§ 6-08(c)(2) and (3) of OATH rules, found in 48 RCNY, and that the hearing officer did not deprive Respondent of a full and fair hearing by declining to order that the IO testify, as the presence of the DOHMH physician, who had knowledge of the records, was sufficient.

ISSUES ON APPEAL

The issues on appeal are (1) whether Petitioner had the authority to issue the summons on the date it was issued; (2) whether Respondent was prevented from having a fair hearing by the

¹⁰ "MMR" stands for Measles, Mumps, Rubella.

¹¹ As part of these arguments, in connection with notice, Respondent references Chapter 45, § 1046, of the New York City Charter (NYCC), and *Matter of Block v. Ambach*, 73 N.Y.2d 323 (1989).

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hearing officer's ruling that it was not necessary for Petitioner to produce the IO for cross-examination; and (3) whether Respondent established a defense to the charge.

APPLICABLE LAW

HC § 3.05(a) provides as follows: "No person shall violate an order of the Board, Commissioner or Department."

HC § 3.01(d) provides as follows:

Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, and during the continuance of such emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health or the safety of the City and its residents. Such procedures, orders or actions may include, but are not limited to exercising the Board's authority to suspend, alter or modify any provision of this Code pursuant to subdivision b of section 558 of the New York City Charter, or exercising any other power of the Board of Health to prevent, mitigate, control or abate an emergency, provided that such exercise of authority or power shall be effective only until the next meeting of the Board, which meeting shall be held within five business days of the Commissioner's declaration if a quorum of the Board can be convened within such time period. . . . At its next meeting, the Board may continue or rescind the Commissioner's suspension, alteration, modification of Health Code provisions or exercise of power.

Code § 17-148(c) provides in pertinent part as follows:

Whenever the board shall have declared any condition, matter or thing to be a nuisance, . . . the board may also take and file among its records what it shall regard as sufficient proof to authorize a declaration that such nuisance is widespread throughout the city or in any area thereof, and that personal service or service pursuant to subdivision a or b of this section of an order or orders requiring the abatement, removal or correction of such nuisance would result in delay prejudicial to the public health, welfare or safety . . . Such order may be served by publishing the same for a period of not less than three days in the City Record and in a newspaper circulated in the area or areas mentioned in such order. Service of such order shall be complete at the expiration of the third day of such publication and such publication shall be sufficient notice of such order and of the nuisance therein mentioned to all persons having any duty or liability in relation thereto under the provisions of this chapter.

ORDER OF THE COMMISSIONER, April 9, 2019, provides in pertinent part:

.

IT IS FURTHER ORDERED that the parent or guardian of any child older than six months of age who lives, works or resides within [four specified ZIP codes] and who has not received the MMR vaccine within forty eight (48) hours of this order being signed by me shall cause such child to be vaccinated against measles unless such parent or guardian can demonstrate that the child has immunity to the disease or document that he or she should be medically exempt from this requirement.

.

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48 RCNY § 6-12(a) provides as follows:

Burden of Proof. The Petitioner has the burden of proving the factual allegations in the summons by a preponderance of the evidence. The Respondent has the burden of proving an affirmative defense, if any, by a preponderance of the evidence.

ANALYSIS

The Tribunal affirms the hearing officer's decision.

The hearing officer credited the testimony and allegations contained in the summons and found they supported a violation of the section cited. The Tribunal generally defers to the hearing officer's credibility determinations and finds no reason not to do so here. *See NYC v. Michele Radolovic*, Appeal No. 44124 (January 18, 2007). The essential facts were not denied. Pursuant to HC § 3.01(d), an Order of the Commissioner of Health was signed on April 9, 2019, requiring that the parent or guardian of any child older than six months, who was living in the designated ZIP codes in Brooklyn and who was not vaccinated against measles, have the child vaccinated within forty-eight hours unless the parent or guardian could demonstrate that the child had immunity or could document that the child should be medically exempt. The Order was enforceable as of April 11, 2019, and remained in effect at least until the BOH met on April 17, 2019. Respondent argues that the summons must be dismissed because it was issued after the Order expired. That is not correct. The summons was based on an examination of Petitioner's records that took place on May 22, 2019. That examination provided uncontroverted evidence that the child was not vaccinated as of the inspection date, thereby also establishing that the child had not been vaccinated during the 48 hours specified in the Order. As the BOH did not rescind or disavow the Order, the Tribunal finds that Petitioner's authority to issue a summons for failure to comply during the specified period was not limited by any subsequent expiration date of the Order. In fact, a summons for a violation that took place during the specified period could have been issued after that period even if the child had subsequently been vaccinated.¹²

Respondent's contention that Petitioner failed to show that medical appropriateness was established was correctly rejected by the hearing officer. By the terms of the Order, Respondent was to demonstrate that the child had immunity or to document that the child should be medically exempt. This was an affirmative defense for Respondent to establish.¹³ There is no evidence in the record to show that Respondent offered any such proof of immunity or documentation, such as a doctor's note, that vaccination was medically inappropriate specifically for this child. In addition, the Tribunal finds the hearing officer's ruling that the IO's appearance was not necessary for a fair hearing to be reasonable. Parties have only a limited right to cross-examination in administrative hearings.¹⁴ Respondent did not offer proof to contest any of the

¹² In this regard, the Tribunal also finds no merit to Respondent's contention that the summons did not provide Respondent with reasonable and accurate notice of the charges as required by 48 RCNY § 6-08(c)(2), in part because it did not inform Respondent of which order he or she was alleged to have violated. The summons was clear in alleging that there was a violation of the April 9, 2019, Commissioner's Order, and the Tribunal finds that the facts alleged in support of that charge satisfy the notice requirements of 48 RCNY § 6-08(c).

¹³ *See DCA v. Best Kept Secret Airport Parking*, Appeal No. 05426379 (November 2, 2018) (after admitting that it was operating a parking lot, Respondent failed to establish that its operation fell under one of the exemptions to the licensing requirement).

¹⁴ *See Gordon v. Brown*, 84 N.Y. 2d 574, 578 (1994) (there is a limited, due process right to cross-examination in administrative proceedings, based upon the nature of the evidence, the burden in producing the requested witness,

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essential facts alleged, and the DOHMH physician, who was available to testify, had personal knowledge of the same vaccination records examined by the IO. As to Respondent's request for dismissal in the interests of justice pursuant to NYCC § 1049, Petitioner is correct that that provision is not applicable to violations of HC § 3.05. It is also noted that Respondent concedes on appeal that the Constitutional objections it raises are beyond the jurisdiction of the Tribunal.

In view of the foregoing, the Tribunal finds that Petitioner had the authority to issue the summons on the date it was issued, that Respondent was not prevented from having a fair hearing by not having the IO present for cross-examination, and that Respondent did not establish a defense to the charge.

Accordingly, the Tribunal affirms the hearing officer's determination that Respondent failed to comply with the Commissioner's Order in violation of HC § 3.05.

By: OATH Hearings Division Appeals Unit

and the potential utility in confronting that witness on the record; there was no need for a lab technician's testimony where the supervisor familiar with each step of the test at issue was subject to cross-examination, and there were no claims of any defects or reliability issues with the test).



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Oxiris Barbot, MD
Commissioner

2019 Health Alert #26: Update on Measles Outbreak in New York City

Distribute to All Primary Care, Infectious Disease, Emergency Medicine, Internal Medicine, Pediatrics, Family Medicine, Laboratory Medicine, and Infection Control Staff

- **Community transmission of measles in Brooklyn has ended.**
- **Maintain a high index of suspicion for measles in persons with a compatible fever and rash illness.**
- **Routine recommendations for administration of the measles, mumps, and rubella (MMR) vaccine are now in effect.**
- **Vaccinate all children with the first dose of MMR vaccine on time at 12 months of age.**
- **Vaccinate children at 6 to 11 months of age prior to international travel or travel to areas with active measles transmission.**
- **Ensure all older children and adults are up to date with MMR vaccine.**

September 3, 2019

Dear Colleagues,

Community transmission of measles in Brooklyn has ended. This is the largest outbreak of measles in the United States since 1992. A total of 654 cases were confirmed, with rash onsets between September 30, 2018 and July 15, 2019. Serious complications included hospitalization (52), intensive unit care (19) and pneumonia (34). Multiple international importations of measles introduced into a community with prevalent delays in vaccination among young children propagated this outbreak.

Although community transmission associated with this measles outbreak has ended, international importations of measles pose a continued risk of outbreaks in New York City. Further, measles cases continue to occur elsewhere in the United States, including in New York State, posing ongoing risk of reintroduction of measles into NYC neighborhoods where there are pockets of unvaccinated individuals, thus re-igniting community transmission of measles. To achieve high population immunity and prevent future outbreaks, providers must ensure that patients receive their first dose of measles, mumps, and rubella (MMR) vaccine at age 12 months and a second dose at age 4 years. Immunizations should be administered on time, with no delay. Providers in previously affected communities no longer need to administer the first dose of MMR vaccine to infants ages 6 to 11 months. However, all children aged 6 to 11 months should receive an early, extra dose of MMR before international travel; this dose does not count towards completion of the routine MMR schedule.

Religious exemptions for all vaccines required to attend school, including MMR vaccine, are no longer valid in New York State. Children should be vaccinated according to state requirements in a timely manner to avoid interruptions in school or day care attendance. Medical exemptions to immunizations are still allowed for children with valid contraindications to immunizations in accordance with the [Advisory Committee on Immunization Practices](#) and are subject to review. [Visit this page](#) for more information.

Persons suspected to have measles should be reported immediately to the New York City Health Department at (866) 692-3641. Reports should be made at time of initial clinical suspicion. Do not wait for laboratory confirmation to report. If you are considering the diagnosis of measles and are ordering diagnostic testing, then you should report the individual at that time. Visit nyc.gov/health and search for "measles and provider" for more guidance. As always, your cooperation is appreciated.

Sincerely,



Demetre C. Daskalakis, MD, MPH
Deputy Commissioner
Division of Disease Control

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Mayor de Blasio, Health Officials Declare End of Measles Outbreak in New York City

September 3, 2019

After a major emergency response and extensive collaboration with community partners, active transmission of measles associated with the 2018-2019 outbreak stops and Emergency Order is rescinded

NEW YORK—Mayor de Blasio and Health Commissioner Dr. Oxiris Barbot today announced the end to the measles public health emergency declared on April 9 for parts of Brooklyn. Measles outbreaks are typically declared over when two incubation periods for measles (the equivalent of 42 days) have passed since the last infectious day of the last persons with measles in affected areas. That time period has now passed for the people most recently infected with measles and reported to the Health Department.

“Ending the measles outbreak required extensive collaboration with community organizations and Jewish leaders. They helped encourage vaccinations and achieve record immunization levels in parts of Brooklyn,” said **Mayor Bill de Blasio**. “As we head back to school this week, we just remain vigilant. To keep our children and communities safe, I urge all New Yorkers to get vaccinated. It’s the best defense we have.”

“Measles is one of the most contagious diseases on the face of the earth,” said **Health Commissioner Dr. Oxiris Barbot**. “There may no longer be local transmission of measles in New York City, but the threat remains given other outbreaks in the U.S. and around the world. Our best defense against renewed transmission is having a well immunized city. Vaccination coverage has increased significantly since the emergency order, which has been supported by community-led efforts. We are grateful to the New Yorkers who shared the truth about vaccines and protected the health of their friends and neighbors through this outbreak.”

Deputy Commissioner for the Health Department's Division of Disease Control Dr. Demetre Daskalakis said, "Staying up to date on vaccines is the best way for people to protect the health and safety of New Yorkers. It only takes one case to start an outbreak. We will continue to urge everyone to confirm that they are immune to measles by looking at their vaccination histories or by consulting with a healthcare provider. Get vaccinated. It is safe and effective."

Ending this outbreak required a major public health response and extensive community collaboration. To battle the outbreak, the City spent over \$6 million and dedicated more than 500 staff to the response; disseminated tens of thousands of pro-vaccination booklets; conducted multiple rounds of robocalls; sent letters and texts to local residents; published ads and distributed educational materials in English, Yiddish, and Spanish; launched an ad campaign that appeared at bus shelters, LinkNYC kiosks, and in newspapers as well as online; hosted a tele-Town Hall to counter anti-vaccination propaganda; visited doctor's offices; and hosted and attended numerous community events, among many other activities.

These efforts were supported by innovative strategies by community members, school and child care administrators and health care providers to counter local misinformation campaigns and stop the spread of measles. These efforts collectively made the community safer and increased vaccination coverage.

Since the outbreak in October 2018, ODA has administered more than 5,000 MMR vaccinations and continues to work to educate area residents about how essential timely vaccinations are to maintaining a healthy family and community.

This was the largest measles outbreak in New York City in nearly three decades.

- Since the outbreak started in October of 2018, 654 individuals were diagnosed with measles.
- There have been 52 measles-related hospitalizations and 16 admissions to intensive care due to measles complications since the beginning of the outbreak.
- Most measles cases were diagnosed in people under 18 years of age (525 cases or 80%).
- Most measles cases were among unvaccinated (73%), incompletely vaccinated (7%) or individuals or persons who did not know their vaccination status (15%).
- While there were cases of measles in all five boroughs, the majority of cases (72%) occurred in the Williamsburg neighborhood (ZIP codes 11205, 11206, 11211, 11249).

In Williamsburg and Borough Park there have been 15,541 doses of the measles-mumps-rubella vaccine administered since the 4/9 Emergency Order, which represents a near 41% increase compared to the same time period last year.

While no new cases have been reported since mid-July, the Health Department will continue monitoring and may add cases retrospectively as they are identified. Those cases will be attributed to the month in which rash onset has occurred. Therefore, the total case count may

increase even after the outbreak is declared over. In addition, New York City may see future measles cases not associated with this outbreak.

Emergency Order Rescinded, Enforcement Continues Due to New State Requirement

Affected ZIP codes have been under an Emergency Order since April 9, requiring people who reside or work in these ZIP codes to be vaccinated or have immunity against measles or face potential fines. With the end of local, active transmission of measles, the April 9th Emergency Order has been rescinded.

Also lifted are the exclusion requirements for unvaccinated children that have been in effect for Williamsburg and parts of Borough Park since December 2018.

While DOH is lifting the exclusion requirements that have been in effect for Williamsburg and parts of Borough Park since December, the effect of the recently enacted State law ending non-medical exemptions for required vaccinations is that children enrolled in school or day care will continue to require the MMR and other vaccines unless they have a valid medical exemption.

Multiple letters have been sent from the City and State to public and private schools, child care facilities, and parents to publicize the new standards.

With schools on notice about the new standards, the Health Department will be rigorously enforcing against non-medical exemptions to ensure that students who can receive the vaccine have done so.

Warning Still in Effect

The threat of measles remains. There are large outbreaks of measles in Europe and Israel, as well as in countries in South America, Africa, and Asia. To protect themselves, New Yorkers should check with their medical provider prior to international travel to make sure they are immune to measles or have been adequately vaccinated before traveling. Infants ages 6 to 11 months should also be vaccinated prior to international travel.

New Yorkers who believe they may have been exposed to measles or who have symptoms of measles should contact their health care provider by phone before seeking care to prevent potentially exposing other patients in healthcare settings.

New Yorkers can call 311 to access a list of facilities that can provide MMR vaccine at low or no cost.

The Health Department is also reminding New Yorkers about the importance of vaccines with a new ad campaign: "Don't Hesitate. Vaccinate!" The campaign reminds parents and guardians to get their children vaccinated on time. The campaign will run online, in bus shelters, subways, and in local newspapers in **English** (PDF), **Spanish** (PDF), Yiddish, and **Traditional** (PDF) and **Simplified Chinese** (PDF). A video version of the campaign featuring Health Commissioner Dr. Oxiris Barbot will run online in **English** and **Spanish**.

"Today's announcement that the measles outbreak is effectively over in New York City is wonderful news and could not come at a better time as students head back to school," said **Council Member Mark Levine, Chair of the Health Committee**. "This success was made possible by aggressive action on the part of DOHMH, as well as bold leadership in the Jewish communities most directly impacted by this outbreak. But our fight against the science denial fueling the anti-vaccine movement continues. Our message is clear: we implore New Yorkers to make sure they and their children are up-to-date on vaccinations."

"I applaud the Department of Health and Mental Hygiene and community leaders for ending the measles outbreak in New York City," said **Council Member Stephen Levin**. "This is great news and thanks to a close public health and community-led partnership. Williamsburg residents can now breathe a sigh of relief, but it is critical we remain vigilant. Measles is an extremely contagious disease and we need to monitor the situation closely as students go back to school. I look forward to continuing to work with stakeholders to ensure New Yorkers have comprehensive information and full access to vaccines; in the midst of ongoing measles outbreaks in the United States and abroad, we cannot be too careful."

"The Orthodox Jewish community takes health seriously. While its vaccination rates have always been high, international travel and a close-knit, family-centered structure left our community particularly vulnerable to the measles, a highly contagious disease," said **Agudath Israel of America Chief of Staff, Avrohom Weinstock, Esq.** We needed to do more. Agudath Israel, and many other dedicated Orthodox Jewish groups and health professionals, took a lead in facilitating public access to vaccines and health information. The redoubling of the community's efforts toward enhancing our already high vaccination rates, while conveying and implementing leading health practices, have helped end this outbreak."

"The measles outbreak highlights how critically important receiving timely vaccinations is to maintaining public health and underscores the vital role community health centers serve in responding to public health emergencies," said **Joseph Deutsch, Chief Executive Officer, ODA Primary Health Care Network**. "We are grateful to our partners at New York City Department of Health and Mental Hygiene who worked tirelessly with our front line staff to address the current outbreak."

Dr. Maureen Nemetski from the Jewish Orthodox Women's Medical Association (JOWMA): "We at the Jewish Orthodox Women's Medical Association are delighted to hear that the measles outbreak in New York City is now over and are glad we were able to do our part to encourage vaccination among the Jewish community. Of course, the threat of re-emergent infections remains present, and we will remain vigilant in our efforts to promote vaccination and vaccine education. In collaboration with the NYC Department of Health and Mental Hygiene and other community partners, we will continue to work tirelessly to safeguard the health of our community and its children."

Media Contact

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(212) 788-2958

office copy

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein, Malky
Roth-Tabak,

Plaintiffs-Petitioners,

Index No. 156722/2020

-against-

Edmead, J.

Department of Health and Mental Hygiene of the City Of
New York,

IAS 35

Defendant-Respondent.

----- X

**MEMORANDUM OF LAW IN SUPPORT OF
CROSS-MOTION TO DISMISS**

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January 4, 2021

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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**MEMORANDUM OF LAW IN SUPPORT OF
CROSS-MOTION TO DISMISS**

PRELIMINARY STATEMENT

Plaintiffs-Petitioners (hereinafter “petitioners”) are eleven parents of eleven children who were not vaccinated against measles at the time of an epidemic in the area where they lived, the Williamsburg area of Brooklyn. They commenced this Article 78 proceeding, styled also as a “declaratory judgment petition,” challenging the public health efforts of defendant-respondent (hereinafter “respondent”), the New York City Department of Health and Mental Hygiene (“DOHMH”), to quell the 2019 epidemic by persuading an increase in the rate of measles vaccination in that area.

Petitioners ask this Court to vacate the civil summonses issued by DOHMH for violation of a DOHMH Order and subsequent Resolution mandating the administration of the vaccine to their children, with a civil penalty as the consequence for non-compliance. These summonses were adjudicated at the New York City Office of Administrative Trials and Hearings

Memorandum in Support of
Defendant’s Cross-Motion to Dismiss

("OATH"). An OATH Hearing Officer found each of the petitioners in violation for having failed to have certain of their children vaccinated against measles, and imposed the \$1,000 civil penalty set forth by DOHMH, which determinations were upheld by the OATH Appeals Unit.

Petitioners seek a declaratory judgment that DOHMH's Order and Resolution mandating the administration of the vaccine or else be assessed a civil penalty after an administrative hearing violated their constitutional rights. They also allege that respondent "acted arbitrarily, capriciously, and contrary to law in rendering the determinations they challenge." The allegation that the determinations were rendered by respondent is erroneous. The determinations were in fact rendered by an OATH Hearing Officer and the OATH Appeals Unit. Petitioners ask this Court to vacate the OATH determinations, even though they failed to name OATH as a party herein. They also seek an award of attorney's fees, costs, and disbursements pursuant to 42 USC 1983 and CPLR 8101.

All of petitioners' arguments fail for the reason described hereinbelow. Petitioners fail to state a cause of action that the determinations rendered against them were arbitrary or capricious. Petitioners have conceded that they did not have the anti-measles vaccine administered to their children. Thus, the determinations that they were in violation of the mandate to do so were intrinsically rational, not arbitrary or capricious.

The constitutional violations alleged by petitioners are predicated on their mischaracterization of DOHMH's orders as mandating forcible vaccination. In fact, DOHMH did not mandate the forcible administration of the vaccination but rather authorized the imposition of civil penalties on petitioners for failure to vaccinate their children.

Finally, attorney's fees are not available in Article 78 proceedings, and they are not available herein pursuant to 42 USC § 1983 because there was no forcible vaccination that might have been deemed to be a constitutional violation.

For all of the reasons set forth herein, the relief contained in the petition must be denied in its entirety.

STATEMENT OF FACTS

Respondent respectfully refers the Court to the Affirmation of Louise Moed, dated January 4, 2021, and the exhibits annexed thereto, in particular, the affirmation of DOHMH Dr. Demetre Daskalakis, Deputy Commissioner of DOHMH's Division of Disease Control that was submitted in the 2019 matter of *C.F. v. DOHMH* (page 9-10 hereinbelow) and is annexed herein as Exhibit 1 (hereinafter the "Daskalakis Aff."). The OATH records for each petitioner are annexed separately to the Moed Affirmation as Exhibits 5-16. References to points in the various hearing transcripts are noted by "Tr" followed by the relevant page numbers.

In brief, as is set forth in the Daskalakis Affirmation, measles is a highly contagious viral disease that can result in serious health complications, such as pneumonia and swelling of the brain. About a third of reported measles cases have at least one complication, and, in some cases, measles can cause death. Measles can be serious in all age groups. However, infants, young children, pregnant women, people whose immune systems are weak, and adults over the age of twenty are more likely to suffer from measles complications. Although measles is highly contagious, the Measles-Mumps-Rubella (MMR) vaccine is a safe and effective vaccine that prevents its transmission.

An active measles outbreak began in early October 2018 in New York City. As of April 15, 2019, the measles outbreak had resulted in 329 reported cases of this vaccine-

preventable disease. In the three prior months, 80% of the cases had been in the Williamsburg, Brooklyn zip codes 11205, 11206, 11211, and 11249. Daskalakis Aff. ¶ 21. The Department had tried multiple strategies to end this outbreak, but the outbreak continued due to low vaccination rates in those four zip codes. The Commissioner determined that the presence of people in Williamsburg lacking the MMR vaccine, with the necessary exception of people who had demonstrated immunity against measles or for whom the MMR vaccine was medically contraindicated (the “two exempted categories”), created an unnecessary and avoidable risk of continuing the outbreak.

As a result, on April 9, 2019, DOHMH Commissioner Oxiris Barbot, M.D., issued an order (the “Order,” annexed to the Moed Aff. as Exhibit 2) mandating vaccination with the MMR vaccine for residents of four zip codes located within the Williamsburg neighborhood of Brooklyn, New York, unless they could establish that they either had immunity to measles, or they produced documentation from a medical professional that they should be medically exempted from the requirement. A failure to comply with the Order could subject an individual to civil penalties. The Order did *not* mandate that people be forcibly vaccinated without consent.

The Order remained in effect until the Board of Health met on April 17, 2019, at which time the Board adopted a Resolution (the “Resolution,” annexed to the Moed Aff. as Exhibit 3) that continued the MMR vaccination requirement but made some minor changes to the exact terms of the Order,¹ none of which altered the applicability of the Resolution to the petitioners herein.

¹ While the Order warned that a violation of New York City Health Code (“HC”) § 3.05 was potentially a criminal offense (which is true of all Health Code violations), that provision was not included in the Resolution, and the Department enforced the Order only by seeking civil

Summonses returnable to OATH were issued to the petitioners, each one predicated on the lack of any record that a particular one of their children (the “subject child”) had either been vaccinated or was in an exempted category. They interposed various defenses that were not valid and none raised as a defense that the subject child had indeed been vaccinated or provided proof that the subject child was in one of the exempted categories. See the Moed Aff. ¶¶ 19-59 and the exhibits referenced thereto.

All eleven petitioners were found to have been in violation, and the \$1,000 penalty was imposed. Those determinations were sustained by the OATH Appeals Unit.

APPLICABLE LAW

New York City Charter

New York City Charter § 556 provides, in relevant part, as follows:

§ 556 Functions, powers and duties of the department [of Health and Mental Hygiene].

Except as otherwise provided by law, the department shall have jurisdiction to regulate all matters affecting health in the city of New York and to perform all those functions and operations performed by the city that relate to the health of the people of the city The jurisdiction of the department shall include but not be limited to the following:

- (a) General functions. (1) Enforce all provisions of law applicable in the area under the jurisdiction of the department for the preservation of human life, for the care, promotion and protection of health. . . .;

penalties of \$1,000 pursuant to HC § 3.11. (HC § 3.11 provides for civil penalties up to \$10,000.) Summonses returnable before OATH were issued, where the civil penalty could be imposed after a hearing.

Memorandum in Support of
Defendant’s Cross-Motion to Dismiss

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(2) supervise the reporting and control of communicable and chronic diseases and conditions hazardous to life and health; exercise control over and supervise the abatement of nuisances affecting or likely to affect the public health.

* * *

The New York City Administrative Code

Administrative Code § 17-142 defines a public health “nuisance” in relevant part, as follows:

The word “nuisance” shall be held to embrace public nuisance, as known at common law or in equity jurisprudence; whatever is dangerous to human life or detrimental to health; . . . and whatever renders the air or human food or drink, unwholesome. All such nuisances are hereby declared illegal.

The New York City Health Code²

New York City Health Code § 3.01 sets forth the general powers of the Department. Health Code § 3.01(c) authorizes DOHMH to “take such action as may become necessary to assure the maintenance of public health, prevention of disease, or safety of the City and its residents.”

Health Code § 3.01(d) states, in part “Where urgent public health action is necessary to protect the public health against an imminent or existing threat, the Commissioner may declare a public health emergency. Upon the declaration of such an emergency, the Commissioner may establish procedures to be followed, issue necessary orders and take such actions as may be necessary for the health and safety of the City and its residents. . . .”

² The New York City Health Code is published as part of Title 24 of the Rules of the City of New York.

Health Code § 3.05 (a) states that “[n]o person shall violate an order of the Board, Commissioner or Department. Pursuant to Health Code § 3.11, violations of the Health Code can be subject to civil enforcement, punishable by a civil penalty. Pursuant to Health Code § 3.12, the Administrative Tribunal established by the Board of Health pursuant to City Charter § 558 is now operated within OATH, and notices of violation or summonses that are issued by DOHMH are adjudicated at OATH.

**New York City Office of
Administrative Trials and Hearings**

Chapter 45-A of the City Charter establishes the New York City Office of Administrative Trials and Hearings (“OATH”). City Charter § 1049-a establishes the Environmental Control Board (“ECB”) as part of OATH. ECB, or the Board, consists of 13 members, including the commissioners of six city agencies - Environmental Protection, Sanitation, Buildings, Health and Mental Hygiene, Police, and Fire. The Board is chaired by the chief administrative law judge of OATH. *Id.* In addition, pursuant to the City Charter, the Board consists of six people to be appointed by the Mayor who are not otherwise employed by the City and who have broad general experience in several areas, including water pollution control, air pollution control, noise pollution control, real estate, and business, as well as a member of the general public. *Id.*

Effective August 7, 2016, 48 RCNY § 6-02 brought the Environmental Control Board (“ECB”) under the auspices of the OATH Hearings Division, which is the tribunal charged with adjudicating summonses formerly returnable at the ECB. ECB now consists of thirteen members, who, among other things, preside over the OATH Appeals Unit and act as

final arbiters on all appeal decisions. As such, the Appeals Unit decision referenced throughout this Memorandum of Law was reviewed, analyzed, and affirmed by the ECB (the Board).

ARGUMENT

POINT I

THE DOHMH COMMISSIONER'S ORDER AND SUBSEQUENT BOARD OF HEALTH RESOLUTION WERE RATIONAL.

A. The Department's Efforts to Increase the Rate of MMR Vaccination Is Based On Nationally Accepted Medical Standards

The safety and efficacy of the MMR vaccine is within the authority and expertise of the United States Centers for Disease Control (the "CDC"). The CDC website contains extensive information on measles and the MMR vaccine. See <https://www.cdc.gov/measles/index.html> and on other webpages found through the embedded links to the measles subsections. The safety of the MMR vaccination and the danger of measles are discussed at <https://www.cdc.gov/measles/vaccination.html>. The current MMR vaccine used in the United States was licensed in 1971 and has a long and strong safety record. Daskalakis Aff. 18.

It was reasonable for DOHMH to follow the public health guidance of the CDC when attempting to quell a measles epidemic in Williamsburg by way of the Order and Resolution, both of which sought to increase the vaccination rate in that neighborhood.

In enacting changes to New York State Public Health Law § 2164 in 1968, the New York State legislature issued the following findings and declaration:

Among the truly great medical advances of this generation have been the development of proved methods of reducing the incidence of smallpox and measles, the once great cripplers. Public health statistics show clearly that immunization is effective and safe.

In fact, the article that first suggested a relationship between the MMR vaccine and brain damage was based on a now-discredited article published in 1998. The supposed finding reported in that article was never reproduced by another scientist, and the article was retracted in 2010. The lead author of that article can no longer practice medicine in the United Kingdom. Since 1999, there have been over 25 articles, including reviews by the Institute of Medicine (source: <http://immunize.org/talking-about-vaccines/mmr.asp>) that have been published in the scientific literature that demonstrate the lack of such an association. Daskalakis Aff. ¶ 18. Moreover, contrary to petitioners' claims, it is not safer and better to get the 'natural' wild-type measles infection. This is demonstrated by the reduction in measles cases and measles deaths in the U.S. and worldwide after the introduction of an effective measles vaccine (80% reduction in deaths from 2000 to 2017, preventing an estimated 21.1 million measles deaths, see <https://www.who.int/en/news-room/fact-sheets/detail/measles>). Daskalakis Aff. ¶ 19. While in some cases a person will develop a rash and/or fever following receipt of the MMR vaccine, the fever and rash are both less serious than natural measles, and are non-transmissible, meaning that other people cannot contract measles by coming in contact with a vaccinated person. Daskalakis Aff. ¶ 19. The various allegations made by petitioners about the MMR vaccine are not supported in the generally accepted medical literature, as the MMR vaccine has a long safety record since being licensed 1971. Daskalakis Aff. ¶ 18.

The risk petitioners believe to be inherent in the MMR vaccine is far outweighed by the City's obligation to protect public health, as explained above. *See e.g. Jacobson v. Massachusetts*, 197 US 11 (1905) Petitioners cite no case law to the contrary.

A challenge similar to petitioners' challenge herein to the safety and efficacy of the MMR vaccine was rejected in *C.F. v. NYC Department of Health and Mental Hygiene*, in a

decision handed down by the Appellate Division, Second Department on December 23, 2020 (a copy of which is appended hereto as Appendix A). The *C.F.* case was commenced during the 2019 Williamsburg measles epidemic to contemporaneously challenge the Order and then the Resolution. The court rejected the validity of the medical opinions submitted by those petitioners in an effort to obtain a preliminary injunction against the same Commissioner's Order and the Board of Health Resolution challenged herein. The court stated as follows:

The petitioners rely on affidavits of doctors opining that the risks of the MMR vaccine outweigh the risks of contracting measles and that vaccinated people are likely a greater threat to public health than unvaccinated people because recently vaccinated people shed the virus. However, in opposition to the petitioners' assertions, the City Health Department's Deputy Commissioner of the Division of Disease Control countered that the petitioners' medical affidavits made many false statements about measles and the MMR vaccine which are not supported in the generally acceptable medical literature and come from persons on the fringes of the medical community. The Deputy Commissioner asserted that the medical consensus is that the MMR vaccine is safe and effective.

An agency's decision to rely on the conclusions of its experts, rather than the conflicting conclusions of challengers' experts, does not render its determination arbitrary, capricious, or lacking in a rational basis (*see Matter of 278, LLC v Zoning Bd. of Appeals of the Town of E. Hampton*, 159 AD3d 891, 894). Here, it was eminently reasonable for the Board to rely on the medical consensus.

Appendix A at 14. *See also* the Daskalakis Aff. (Exhibit 1).

B. The DOHMH Order and the Board of Health Resolution Were Rational.

The Order and the Resolution that continued it were reasonable and rational, fell fully within the powers of the Commissioner and the Board of Health, and did not violate the

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federal or state Constitutions. The Department pursued a multi-faceted approach to persuade residents of Williamsburg to be vaccinated with the MMR vaccine (Daskalakis Aff. ¶¶ 22-28). In fact, the measles epidemic in Williamsburg was quelled by the middle of July 2019 (Exhibit 17).

Pursuant to New York City Charter § 556, the Department is responsible, among other things, for controlling communicable diseases within the City of New York and for supervising the abatement of nuisances that affect or are likely to affect the public health.

Measles is easily transmitted from a sickened person to others who lack immunity to the disease. Measles is one of the most contagious of all infectious diseases: up to 9 out of 10 susceptible people (90%) who come into contact with a measles patient, or a space where a measles patient recently has been, will develop measles. The virus is transmitted by direct contact with infectious droplets or by airborne spread when an infected person breathes, coughs, or sneezes. The virus can live for up to two hours in the air or on surfaces where an infected person coughed or sneezed, and people who lack immunity are highly likely to become sick if they are in contact with an infectious person or near where an infectious person has recently been. If other people breathe the contaminated air or touch the infected surface, then touch their eyes, noses, or mouths, they can become infected. A person can spread measles from four days before through four days after the appearance of the rash that is a recognizable measles symptom. Daskalakis Aff. ¶ 9.

At the time the Order was issued and the Resolution subsequently adopted to continue the public health measure contained in the Order, there was an active measles outbreak within New York City. The outbreak of this vaccine-preventable disease began in early October 2018. As of April 15, 2019, that is, shortly before the Board of Health adopted its Resolution,

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there had been a total of 329 reported measles cases in NYC during that outbreak, 267 of which had been in Williamsburg. At that point, twenty-five individuals had been hospitalized, of whom 6 were in intensive care. Daskalakis Aff. ¶¶ 20-21.

The Department had tried multiple strategies to end this outbreak, including intensive outreach to the affected community and the healthcare providers who served them. Additionally, the Department of Health required unvaccinated children to be excluded from yeshivas and child-care programs serving that community. However, the outbreak continued, due to low vaccination rates. Daskalakis Aff. ¶¶ 22-27. Moreover, because of the high rate of people living in Williamsburg who had not been vaccinated against measles despite the efforts of the DOHMH to increase vaccination in that area, the measles outbreak persisted in zip codes 11205, 11206, 11211, and 11249. Daskalakis Aff. ¶ 28.

Pursuant to Health Code § 3.01, the DOHMH Commissioner has authority to declare a public health emergency when there is an urgent threat to the health of New York City residents, and to take such actions that the Commissioner deems necessary for the health and safety of the City and its residents when urgent public health action is necessary to protect the public health against an existing threat. The Commissioner reasonably determined that an unnecessary and avoidable risk of a continuing measles outbreak was being created by the presence in Williamsburg of people lacking the MMR vaccine. Thus, it was reasonable and rational for the Commissioner to declare a public health emergency on April 9, 2019, and issue the Order in response to the measles outbreak in zip codes 11205, 11206, 11211, and 11249.

The incidence of measles in the City, especially in the affected zip codes is well-documented. In addition, the CDC defines even three cases of measles as constituting an outbreak. Daskalakis Aff. ¶ 15. Thus the incidence of measles in New York City in April 2019,

and in the affected zip codes was far in excess of the number that is recognized as an outbreak. Furthermore, the incidence of new measles cases in the affected area continued to increase. Daskalakis Aff. ¶ 30. Thus, the Commissioner's declaration of a public health emergency was neither arbitrary nor capricious, and petitioners have failed to show that the Order was arbitrary or capricious.

DOHMH was rational and acting well within its mandate and authority to proceed in conformance with the national standard of care regarding measles that has been set by the CDC. The medical standard of care regarding the MMR vaccine has been established. Petitioners do not have a valid defense when they argue against the validity of that standard of care.

POINT II

THE OATH DETERMINATIONS THAT PETITIONERS WERE EACH IN VIOLATION WERE, AS A MATTER OF LAW, RATIONAL AND NOT ARBITRARY OR CAPRICIOUS.

A. Petitioners Concede That They Were In Violation As Was Found At OATH.

The OATH determinations challenged herein³ were indisputably rational and not arbitrary or capricious, as evidenced by the fact that petitioners concede in the petition that they committed the charged violations:

6. Plaintiffs-Petitioners had a reasonable and well-founded belief that they should not administer the MMR to their children (the "children") for many reasons....

³ Petitioners erroneously allege that the determinations were made by respondent, DOHMH, and petitioners failed to name OATH as a respondent herein. DOHMH nonetheless defends herein the rationality of those determinations, which upheld DOHMH's public health measures.

As is clear in the transcripts in the accompanying exhibits, no respondent raised as a defense to any summons the defenses provided in the Order and the Resolution: that the subject child was in an exempted category, that is, immune to measles or that the subject child had a documented medical condition that contraindicated the administration of the MMR vaccine to that child and warranted an exemption. Nor did any of them offer proof that the subject child had indeed been administered the MMR vaccine.

B. The Defenses Interposed by Petitioners Were Not Valid Defenses to the Public Health Measures Contained in the Order and Resolution.

On behalf of all of the petitioners, petitioners' attorney interposed as a defense to the Order their assertion that the MMR vaccine was medically unsafe and ill-advised as a matter of general public health. *See* the Tabak transcript generally, petitioners' OATH exhibits (Petition Exhibits A-XX, NYSCEF Document Nos. 4-53), petitioners' OATH appeals briefs (included in Exhibits 6-16 to the Moed Aff.), and the petition and memorandum of law. *See also* Point I hereinabove.

None of the other defenses asserted by petitioners were valid defenses against either complying with the Order or being liable for the civil penalty. Therefore, it was rational to find petitioners in violation.

A Child's Medical Condition

No respondent proffered evidence of meeting the requirements for having the subject child be exempted from being vaccinated, *i.e.*, that the child was already immune to measles or that a medical practitioner had submitted documentation attesting to a medical contraindication warranting exemption of that child from the vaccine.

Petitioner Berkowitz raised as a defense that the subject child had had eye surgery (Exhibit 11 at Tr 6-7) and petitioner Friedman asserted the defense that the subject child was sick on the date the summons was issued (Exhibit 13 at Tr 6). DOHMH's medical witness, Dr. Jennifer Rosen, Director of Epidemiology and Surveillance for DOHMH's Bureau of Immunization, testified that those medical situations did not constitute contraindications to receiving the MMR vaccination, and it was also clear that there had been many dates after the issuance of the Order and Resolution and prior to the summons dates on which each of those children did not have the claimed medical conditions and could have been vaccinated (Exhibit 11 at Tr 8-9, Exhibit 13 at Tr 7). Petitioner Englander claimed that the subject child was not immunologically capable of handling the MMR vaccine (Exhibit 7 at Tr 14-15). But neither she nor petitioners Berkowitz or Friedman submitted documentation from a medical practitioner attesting that the subject child's medical condition warranted a medical exemption (Exhibit 5 at Tr 98-105, Exhibit 7 at Tr 15-17; Exhibit 11 at Tr 7-8, Exhibit 13 at Tr 7). *See* DOHMH's FAQ regarding the Order at 3 (Exhibit 4 to the Moed Aff.).

Petitioners Fishman and Fried declined to have the subject child vaccinated because a sibling had supposedly had a bad reaction to it (Exhibit 12 at Tr 8-9 and Exhibit 14 at Tr 11). Dr. Rosen testified that that was not a medical contraindication to MMR vaccine based on national Advisory Committee on Immunization Practices guidance (Exhibit 12 at Tr 9-11 & Exhibit 14 at Tr 13).

The Application of the Order to a Child Under Twelve Months Old

Petitioner Hauer, Fried, and Fulop each challenged the applicability of the Order to their child who was under 12 months of age, which is the usual age at which the first MMR vaccination is recommended (Exhibit 8 at Tr 9-10, Exhibit 14 at Tr 11-12, and Exhibit 16 at 5-6).

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Dr. Rosen testified that the Advisory Committee on Immunization Practices, which sets the national recommended schedule for immunizations, recommends that an additional, early dose of the MMR vaccine can be administered to children ages six to eleven months during a measles outbreak (Exhibit 8 at Tr 10-11, Exhibit 14 at Tr 12-13, Exhibit 16 at Tr 7-8).

Religious Objections

Petitioners Fishman, Friedman, Fried, Josef, and Fulop asserted a religious exemption from having the MMR administered to their children (Exhibit 12 at Tr 12, Exhibit 13 at Tr 6-7, Exhibit 14 at Tr 12, Exhibit 15 at Tr 5, and Exhibit 16 at Tr 6). However, neither the Health Code, the Order, nor the Resolution contains any such defense.

The invalidity of a religious defense to the Order was upheld in *C.F. v. NYC DOHMH*, in the Second Department's December 23, 2020 decision (Appendix A). The court found as follows:

We believe that the Free Exercise Clause does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability, even if the law has the incidental effect of burdening a particular religious practice.

Appendix A at 20.

* * *

The Board [of Health]'s resolution does not target religion or single out religion; it does not even mention religion. There is absolutely no indication that the resolution was adopted for the purpose of infringing the petitioners' religious practices or suppressing their religious views (*see Parents for Privacy v Barr*, 949 F3d at 1235). The resolution treats all persons equally, whether religious or not (*see id.* at 1236). The resolution does not create any favored classes at all, much less ones that are secular rather than religious. As the resolution is religiously neutral and generally applicable, it is not subject to strict scrutiny.

The Board surely had a rational basis to mandate vaccination for virtually all persons residing, working, or going to school within zip codes with a measles outbreak. The petitioners' religious beliefs do not excuse them from compliance with an otherwise valid legal obligation of general applicability (*see Employment Div., Dept. of Human Resources of Oregon v. Smith*, 494 US at 879-880).^[4]

Even if strict scrutiny applied, the Board's resolution is nonetheless valid as there is a plain and compelling interest in controlling a measles outbreak, and the resolution was narrowly tailored to advance that interest, as shown by the geographic limitation to an area in which the contagion was widespread, the Board's prior, unsuccessful efforts to stem the outbreak, and the temporal limitation of the resolution to the duration of the outbreak. Individuals within the affected area could accept the vaccine, pay a fine, seek a medical exemption, or temporarily relocate out of the narrowly drawn impacted area.

Appendix A at 21-22.

In the months following the measles outbreak, religious leaders in the Orthodox Jewish community urged parents to vaccinate their children. *See, e.g.:*

<https://nypost.com/2019/04/12/yiddish-newspaper-publishes-editorial-to-support-vaccinations-amid-measles-outbreak/>

<https://www1.nyc.gov/site/doh/about/press/pr2018/pr091-18.page>

In addition, an April 2019 newspaper article reported that over 500 doctors serving Jewish communities across North America had signed a letter that confirmed the need for children and adults to get immunized:

⁴ 494 US 872 (1990)

<https://www.theyeshivaworld.com/news/general/1715579/unprecedented-over-five-hundred-doctors-serving-jewish-communities-across-north-america-say-vaccinate.html>

Challenges to the Service of the Summonses

Petitioners Hauer, Biederman, Fishman, and Fulop challenged the service of the summonses issued to them (Exhibit 8 at Tr 6-9, Exhibit 9 at Tr 6-7, Exhibit 12 at Tr 6-7, and Exhibit 16 at Tr 6). The Hearing Officer found no merit in any of those challenges, especially in light of the fact that no respondent denied having actually received the summons.

Thus, petitioners failed to raise any defense that the charges in the summonses were untrue. It was therefore rational and not arbitrary or capricious for the Hearing Officer to have found petitioners in violation of the DOHMH requirement that their children, who lived in one of the zip codes in which there was a measles epidemic at the time the summonses were issued, be given the MMR vaccine or else have the parents be assessed a civil penalty. Furthermore, it was rational and not arbitrary or capricious for the OATH Appeals Unit to issue appeals decisions sustaining the determinations of the Hearing Officer.

Thus, petitioners do not have a cause of action pursuant to Article 78 to review whether the OATH findings had a rational basis in the administrative record. Petitioners have admitted herein to the violations as charged. Thus, it was not arbitrary or capricious for the OATH hearing officer and the Appeals Unit to find that the petitioners were in violation of the requirement that the MMR vaccine be administered to their children.

C. The Order and the Resolution Were Completely Consistent, and the Differences Between Them Were *De Minimus* and Of No Moment With Respect to Petitioners.

The Commissioner's Order and the Board of Health Resolution were completely consistent in addressing the measles epidemic in Williamsburg, and the differences between them were *de minimus* and of no moment with respect to petitioners.

Petitioners point to *de minimus* differences between the wording of the Order and the Resolution, and argue that those differences violated their due process rights (Pet. ¶¶ 24-26). However, both documents contain the exact same requirements that petitioners were charged with violating and that petitioners concede they violated: that the parent or guardian of a particular child older than six months who lived within certain zip codes, which were in Williamsburg, were to cause the identified child to be vaccinated against measles unless able to demonstrate that the child was in an exempted category, that is, had immunity to measles or could provide documentation from a medical provider that the child should be medically exempt from the vaccination.

Notwithstanding minor wording differences between the Order and the Resolution, both of them mandated the administration of the MMR vaccine to petitioners' children. None of the differences had any bearing on the mandate as it applied to petitioners and their children. As was found by the OATH Hearing Officer in each of his hearing decisions:

I find that the NYC Health Board, by its April 17, 2019 Resolution, continued the Commissioner's exercise of emergency authority, which operated to continue the validity of the Commissioner's April 9, 2019 Order.

D. Petitioners' Challenge to the Viability of the Order on the Day the First Summons Was Issued Is Meritless.

Petitioners attempt to undermine the validity of the summons issued against petitioner Malky Tabak on the basis that the Board of Health's Resolution had not been published for three days prior to the April 21, 2019 issuance of the summons as required by Admin. Code § 17-148(c) (Exhibit 5 at Tr 64-66). DOHMH's General Counsel argued that the Order was continued by the April 17, 2019 Resolution and was still in effect on April 21 (Exhibit 5 at Tr 66-68). Petitioners' counsel took a position contrary to the public health emergency that was present at that time. In arguing that on April 17, 2019, the Board of Health, by adopting the Resolution, extinguished the Order, but that the Resolution was not in effect until after its publication on April 22 through 24, he was arguing in favor of a mandatory gap in the Department being able to address the then-present danger of the measles epidemic. DOHMH's General Counsel argued that the remedial action of mandating vaccination continued to be in effect, whether by the Commissioner's Order or by the Board of Health's Resolution, and he pointed to the Resolution's own final statement that it was to take effect immediately (Exhibit 3 and Exhibit 5 at Tr 76-78).

POINT III

NEITHER THE ORDER NOR THE RESOLUTION VIOLATED ANY FEDERAL OR STATE CONSTITUTIONAL RIGHTS IN THAT THEY DID NOT MANDATE THE FORCIBLE ADMINISTRATION OF THE MMR TO PETITIONERS' CHILDREN.

Petitioners claim that requiring the injection of the MMR vaccine into their children violated their rights under the United States and New York State Constitutions (petition ¶¶ 62-94). However, petitioners mischaracterize the content of the Commissioner's Order and

the subsequent Board of Health Resolution. Neither mandated the forcible administration of the MMR injection to their children. While the Order mandated vaccination for people who were not immune to the measles virus or not exempt because of a medical contraindication, people were not required to be vaccinated against their will. Rather, non-compliance subjected an individual to possible civil penalties, after receiving a summons and an opportunity to be heard at an administrative hearing in the OATH Hearings Division. Daskalakis Aff. ¶ 41.

Because the Order and Resolution violated no constitutional right, no attorneys' fees can be awarded to petitioners pursuant to 42 USC § 1983.

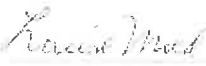
CONCLUSION

Petitioners have failed to establish that the lack of a rational basis for the determinations at OATH that they were in violation of the DOHMH Order and Board of Health Resolution. Rather, they have conceded that they *were* in violation without the valid defense of either immunity to measles or the basis for a medical exemption as attested to by a medical professional. *See* Point I hereinabove. The petitioners have failed to show that the Order and Resolution lacked a rational basis, as those orders were in conformance with the national standards for preventing and addressing a measles epidemic. Finally, they also failed to show that the Order violates their constitutional rights, as no forcible vaccination was ordered by DOHMH. *See* Point III hereinabove.

For the foregoing reasons, the petition should be denied and the instant proceeding dismissed in its entirety.

Dated: Brooklyn, New York
January 4, 2021

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Memorandum in Support of
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**SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK**

Ascher Berkowitz, Chava Biederman, Beila Englander,
Israel Fishman, Judith Fried, Malka Friedman, Chanie
Fulop, Rachel Guttman, Simon Josef, Baila Klein,
Malky Roth-Tabak,

Plaintiffs-Petitioners,

v.

Dept. of Health & Mental Hygiene of the City of New
York

Defendant-Respondent.

**REPLY IN FURTHER SUPPORT
OF THE VERIFIED ARTICLE 78
AND DECLARATORY
JUDGMENT PETITION**

&

**OPPOSITION TO DEFENDANT'S
CROSS-MOTION TO DISMISS**

Index No. 156722/2020

Plaintiffs (“**Plaintiffs**”) respectfully submit their reply in further support of their petition and in opposition to the cross-motion to dismiss filed by Defendant-Respondent (“**Defendant**”).¹

**FIRST CAUSE OF ACTION: THERE WERE ERRORS OF LAW IN DEFENDANT'S
FINAL DETERMINATIONS**

(Relief Under Article 78 of the CPLR)

1. Defendant’s opposition and cross-motion fail to rebut that the Summonses were invalid on their face because they charged Plaintiffs with violating an order that had already expired.

2. Defendant does not contest that it is black letter law that a summons must identify the exact law, regulation, or order that the charging officer claims the recipient violated. RCNY § 6-08(c)(2) and (c)(3). The Commissioner’s Order was issued on April 9, 2019 (**Ex. C**) and expired on April 17, 2019 (*see* Health Code of the City of New York, 24 RCNY § 3.01(d) and **Ex. D** at **56:34-57:7; 63:23-64:2**). The Summonses charge the Plaintiffs with violating the Commissioner’s Order (**Ex. F**) but were each issued *after* April 17, 2019 and each list a “Date and

¹ All Exhibits referenced in this Petition are exhibits admitted without objection at the OATH hearing and are part of the administrative record. It also noted that the Affirmation of Louise Moed in Support of Defendant’s Cross Motion to Dismiss mischaracterizes portions of the OATH hearing at issue and Plaintiffs respectfully submit that the transcript of the hearing (**Ex. D**) speaks for itself.

Time of Occurrence” for the purported violation *after* April 17, 2019. (Ex. [F.](#)) The Summons are therefore invalid and must be dismissed.

3. Defendant defends this fatal defect by claiming that the Commissioner’s Order was continued by the Board’s Resolution of April 17, 2019. (Ex. [E.](#)) This defense must fail because nowhere in the Board’s Resolution does it state it continued the Commissioner’s Order. *Id.* That the Board’s Resolution did not continue the Commissioner’s Order is not surprising because, as detailed in the Petition, the Resolution is significantly different from the Order, including as to the prohibited conduct, the population subject to the order, and the penalty. (Petition ¶¶ 23-27.) This is precisely why nowhere in the Resolution does it ever state that it is continuing the Commissioner’s Order. The Resolution, while covering a similar topic as the Order, plainly created a new and distinct order.

4. The New York City Health Code provides that “the Board may *continue* or *rescind*” the Order. Health Code of the City of New York, 24 RCNY § 3.01(d) (emphasis added). On its face, that section allows the Board only to continue the order “as is” or to rescind the order and issue a new order. Nothing in that section states that the Board may *amend* the emergency order and the Defendant did not interpose any argument to the contrary.²

5. Tellingly, the OATH Appellate Unit did not affirm the OATH Hearing Officer’s flawed conclusion that the Resolution continued the Order. The OATH Appellate Unit apparently found it to be without merit. Instead, it decided that since the children presumably did not have the MMR during the period the Order *was* in effect, then it would uphold the Summonses by

² Contrary to Defendant’s claim (Defendant’s MOL at 20), there would not be a three-day or any gap in enforcement when a Commissioner’s order is continued by the Board. *See* Health Code of the City of New York, 24 RCNY § 3.01(d). But where a continuation does not happen, and the Board issues a new order, rather than continuing the Commissioner’s order, as it did here, then the relevant law does require a three-day publication period. *See* Admin. Code § 17-148(c).

effectively rewriting them; instead of the “Date and Time of Occurrence” for the violation listed on the Summonses, it decided it would simply find the Plaintiffs in violation of a completely different time period. The problem with the OATH Appellate Unit’s decision is that it changed the Summonses that were being adjudicated *ex post facto* – after the hearing record was closed – which it cannot do. It is elementary and critical to due process that a respondent only be judged on and punished for what a summon charges. Here, that charge was for violation of the Order on a date after it expired, not for a violation that occurred on some other date first raised in a decision by an appellate body. That is the antithesis of due process and the orderly manner in which justice is supposed to proceed. Indeed, Plaintiffs’ counsel prepared its defense based on the Summonses, as written, and not on the rewritten version fabricated by the OATH Appellate Unit.

6. In sum, the Order had expired by the time the Summonses were issued, and it was an error of law for the Hearing Officer and Appeals Unit to affirm the Summonses because the Commissioner’s Order had expired by the date of the occurrence listed on the Summonses.

SECOND CAUSE OF ACTION: NYCC § 1049(5)(a) CALLS FOR THE DISMISSAL OF THE SUMMONSES IN THE INTEREST OF JUSTICE

(Relief Under Article 78 of the CPLR)

7. Defendant also fails to rebut that the Summonses should have been dismissed pursuant to NYCC § 1049(5)(a) because the undisputed evidence entered at the hearing reflected that the risks of injecting the MMR into Plaintiffs’ children outweighs any benefits.

8. The uncontroverted evidence reflects that:

- The first vaccine for measles was licensed in the United States in 1963 and, according to the CDC, the mortality rate from measles declined by over 98% between 1900 and 1962. (Exs. [A](#) and [B](#).)

- In the years leading up to 1963 (when no measles vaccine existed), the CDC reported a total of approximately 400 deaths from measles per year in the United States during a time when virtually every American had measles, reflecting an annual death rate from measles of 1 in 500,000 Americans prior to the introduction of the measles vaccine. (Ex. [B](#); Ex. [D](#) at 207:18-21.)³
- Eliminating measles has demonstrably and measurably increased certain cancer rates, the risk of heart disease, and other serious medical conditions:
 - The International Agency for Research on Cancer has confirmed that those who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma and a 233% increased rate of Hodgkin Lymphoma. (Exs. [L](#), [M](#), [N](#), [O](#) and [P](#).) These two cancers killed **20,960** Americans in 2018. *Id.*
 - Likewise, researchers at the Department of Health Care and Epidemiology at the University of British Columbia and the Department of Biology at the University of Victoria have confirmed that those who never had measles had a 50% increased rate of ovarian cancer, which killed **14,070** Americans in 2018. (Exs. [Q](#) and [R](#).)
 - The nation of Japan concluded, after tracking over 100,000 of its citizens for more than 22 years, that having measles and mumps was “associated with lower risks of mortality from heart disease,” which killed **610,000** Americans in 2018. (Exs. [S](#) and [T](#).)

³ Medical care for acute viral infections has also made significant advances since 1962.

- Additionally, Exhibits [I](#), [J](#) and [K](#) reflect that children who have had measles have far less allergies and atopic diseases, such as asthma, and adults who had measles have a reduced risk of Parkinson's Disease.⁴

9. Hence, the un rebutted evidence shows that eliminating measles has caused far more deaths annually in the United States from cancer and heart disease than the potentially few hundred lives saved from elimination of measles.⁵

10. **The foregoing un rebutted facts presented at the hearing demand that the Summonses be dismissed because the accepted and un rebutted evidence demonstrates an increased, not decreased, risk of mortality from complying with the Order. Defendant was given repeated opportunities, including during a follow-up hearing weeks later, to rebut this evidence but had nothing to present in rebuttal despite repeated requests from the OATH hearing officer.** (Petition ¶¶ 43-45, 58-59.)

11. In their papers, Defendant improperly submit an affirmation of Dr. Demetre Daskalakis, dated April 16, 2019, that was filed in another matter. Unsurprisingly, because it was prepared before the OATH hearings in this matter, it fails to address the evidence presented by Plaintiffs. Putting aside that it makes claims that are unsupported by the data regarding measles or the MMR vaccine⁶, even accepting its inaccurate claims, it fails to discuss the far greater lifetime risks of disease and death caused by preventing measles, *supra*, nor the evidence detailed *infra*.

⁴ It is not medically appropriate or just to increase an individual's risk of allergies, atopic diseases, or Parkinson's.

⁵ Stated differently: until the introduction of the vaccine, measles was considered a mild childhood infection, like the chickenpox; the ecological relationship humans developed with measles through millennia did not eliminate measles; and the evidence presented at the hearing supports that having measles conferred benefits for survival that exceeded its negative effects.

⁶ Daskalakis' affirmation vastly overstates the risk of measles and understates and largely ignores the risks from MMR vaccine. For example, he raises fear that measles can cause subacute sclerosing panencephalitis (SSPE), a fatal disease, but fails to disclose that the measles vaccine can also cause SSPE.

12. In any event, Daskalakis's affirmation is *not* properly before this Court as it was not part of the record at OATH and must be disregarded. See, e.g., *Rizzo v. N.Y. State Div. of Hous. & Cmty. Renewal*, 16 A.D.3d 72, 75 (1st Dep't 2005) ("Judicial review of the propriety of an administrative determination is limited to those grounds invoked by the agency in its determination ... and 'the court may not consider arguments or evidence not contained in the administrative record.'") (internal citations omitted); *Fanelli v. New York City Conciliation & Appeals Bd.*, 90 A.D.2d 756, 757 (1st Dep't 1982) ("The function of the court upon an application for relief under CPLR article 78 is to determine, upon the proof before the administrative agency, whether the determination had a rational basis in the record or was arbitrary and capricious. Disposition of the proceeding is limited to the facts and record adduced before the agency when the administrative determination was rendered.")

13. Defendant also addresses affidavits apparently submitted by numerous physicians that are not part of this case but another matter and are therefore wholly irrelevant. Plaintiffs never adopted the affidavits or positions of those other physicians nor incorporated them into this matter. Unlike those affidavits or the affidavit attached to Defendant's papers, Plaintiffs relied on the hard data and peer-reviewed studies, *supra* and *infra* – not conclusory assertions. As Defendant appears unable to address that data and science, it deflects by attacking affidavits from physicians in

See <https://www.cdc.gov/mmwr/preview/mmwrhtml/00001185.htm>. Daskalakis asserts that measles can cause brain swelling but fails to disclose that the MMR can also cause brain swelling and, as confirmed by the CDC, brain damage. (Ex. **KK**) (The CDC's Vaccine Information Statement for the MMR vaccine warns it can cause "Brain damage.") Daskalakis also fear mongers by using misleading measles death figures from developing countries that are irrelevant to developed countries, such as the United States, where the measles death rate was brought down by over 98 percent without any measles vaccine through improvements in clean water, nutrition, and sanitation. (Ex. **B**.) Daskalakis even wrongly claims "[t]he current MMR vaccine used in the United States was licensed in 1971" when it was in fact licensed in 1978. (Ex. **BB**.) Daskalakis is, with little doubt, well-meaning but his affirmation, beyond its inaccuracies, is a litany of unsupported assertions that ignores the actual data and studies regarding measles and MMR vaccines.

another matter that Plaintiffs have never adopted let alone referred to in this matter in any way whatsoever. (Defendant's MOL at 9-10.)

14. In addition, the following are a few of the additional facts regarding the MMR vaccine used in the United States, M-M-R-II⁷, that are also unrebutted:⁸

- The clinical trial relied upon by the FDA to license M-M-R-II had a total of 834 children, had no placebo control, and only reviewed safety for 42 days after injection. (Ex. [BB](#).) It was therefore incontrovertibly underpowered, not properly controlled, and did not review safety for a long enough period of time.
- After licensure, Exhibits [EE](#), [FF](#), [GG](#), [HH](#) and [II](#) are reports from the Institute of Medicine ("IOM") which reviewed 22 of the most commonly claimed serious injuries from the MMR vaccine. For 18 of the 22, the IOM was *not able to determine* whether or not the MMR caused them due to a *lack of science*, explaining: "The lack of adequate data regarding many of the adverse events under study was a major concern to the committee." The IOM further explained that "most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility" yet no studies have been conducted to identify these individuals. (Ex. [II](#).)
- After licensure, federal law expressly provides that the package insert for a vaccine like M-M-R-II should include "*only* those adverse events for which

⁷ Ex. [V](#) lists the excipient and media contained in the MMR, including but not limited to, chick embryo cell culture, WI-38 human diploid lung fibroblasts, human albumin, bovine calf serum, and neomycin. Exs. [W](#) and [Y](#) are product descriptions and history of the use of these ingredients and excipients. Ex. [Z](#) and [AA](#) explain the existence of aborted fetal cells' use in vaccines and the potential adverse effects of such use.

⁸ Physicians have separately detailed the benefits and risks of the MMR in Ex. [A](#).

there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.” (Ex. [D](#) at 217:19-218:16.) The package insert for M-M-R-II lists approximately 60 such adverse reactions that Merck has identified, many of which are serious and debilitating. (Ex. [DD](#).) For instance, Merck added “transverse myelitis” in 2014 and “Henoch-Schonlein purpua” and “acute hemorrhagic edema of infancy” in 2017. (Ex. [JJ](#).)

- The CDC also discloses that MMR vaccine can cause deafness, long term seizure, coma, and brain damage.⁹ (Ex. [KK](#).) An example of such an injury involved a \$100 million award to the victim of an MMR injury. (Ex. [LL](#).)
- This high rate of hospitalization and emergency room visits from MMR vaccine is confirmed in a study conducted by Canadian health authorities of 271,495 children after their 12-month MMR. This study set out to confirm the safety of MMR, but what they found instead was that “[t]here was a significantly elevated risk of primary emergency room visits approximately one to two weeks following 12- and 18-month vaccination.” (Ex. [MM](#).) This amounted to an additional “one event for every 158 vaccinated” children receiving MMR. Extrapolating these figures to the United States, 63,291 additional American children visit the emergency room each year because of the MMR program.

15. What makes the foregoing un rebutted evidence even more concerning is that after the current MMR’s licensure in 1978, its use in children steadily increased and lawsuits from injuries from this product rose in tandem. Indeed, by the mid-1980s – when the only two

⁹ The MMR vaccine has also never been evaluated for its potential to cause cancer, to mutate genes, or to cause infertility. (Ex. [DD](#).)

commonly injected childhood vaccines were MMR and DTP – pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products. (Ex. [D](#) at 184:24-186:18, Ex. [NN](#).) See also *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011) (“by the mid-1980’s ... the remaining [vaccine] manufacturer estimated that its potential tort liability exceeded its annual sales by a factor of 200.”)

16. Instead of letting the usual market forces drive pharmaceutical companies to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act in 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34, which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccine products. 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”). While Merck, the company that sells the MMR, has paid billions of dollars for misconduct and injuries related to its drug products, it cannot be held accountable for misconduct and injuries resulting from its MMR vaccine product.

17. When provided an opportunity to rebut any of the foregoing evidence, the DOH did not proffer any evidence in rebuttal, accepted the foregoing evidence without objection, and despite prodding from the Hearing Officer, neither the DOH nor Dr. Rosen had any additional argument, statement, or evidence to present to rebut any of the foregoing. (Petition ¶¶ 43-45, 58-

59.) Thus, the undisputed evidence reflects that MMR was not medically appropriate for Plaintiffs' children, as the risks of injecting this product into the children outweigh the benefits.¹⁰

18. Imposing a fine on these families for choosing what the evidence reflects is best for their children's overall health is unjust. The NYSDOH had every opportunity to present data and peer-reviewed studies reflecting that the data and peer-reviewed studies presented were incorrect. Defendant could not. The Court, respectfully, must therefore find that the final determinations against Plaintiffs are affected by an error of law and are arbitrary and capricious.

**THIRD CAUSE OF ACTION: REQUIRING INJECTION OF M-M-R-II VIOLATES
THE UNITED STATES AND THE NEW YORK CONSTITUTIONS**

(Declaratory Relief Under Article 30 of the CPLR)

19. For the same reason that Defendant failed to rebut that the Summonses should be dismissed as unjust, Defendant failed to rebut that the Summonses should be dismissed based on violations of the of the United States Constitution and the New York State Constitution. Because the un rebutted record reflects that the risk of injecting the product at issue outweigh its benefits, including a significant increased risk of mortality, Plaintiffs' fundamental constitutional rights act as a shield of protection to prevent the government from requiring such an injection, including federal and state constitutional rights to substantive due process, bodily integrity, informed consent, parental choice, privacy, unlawful search and seizure, other unenumerated rights, and the First Amendment. The reasoning and argument for violating each of these protections is set forth in detail in the Petition. Defendant fails to rebut the evidence supporting and the grounds for affirming these constitutional violations.

¹⁰ Indeed, the one study that looked at health outcomes of children who were vaccinated versus children who were not vaccinated found that vaccinated children had a higher rate of several forms of chronic illness and neurodevelopmental disorders than the unvaccinated. See **Ex. PP**. It is not medically appropriate or just to force an individual to trade avoidance of a limited infection for a chronic health condition.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully repeat their request that this Court enter an Order:

- (a) Declaring, pursuant to CPLR § 7803, that Defendant acted arbitrarily, capriciously, and contrary to law by issuing its final determinations in the manner described herein;
- (b) Declaring, pursuant to CPLR § 3001, that the Commissioner's Order and the Resolution violate the New York and United States Constitutions;
- (c) Setting aside and vacating the Summonses;
- (d) Awarding Plaintiffs reasonable attorney's fees, costs and disbursements pursuant to CPLR § 8101, 42 U.S.C.A. § 1983, any other applicable statutory, common law or equitable provision, and that any defense as to the validity of the Summonses is without merit; and
- (e) Granting such other and further relief as the Court deems just and proper.

Dated: April 13, 2021

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

----- x

Ascher Berkowitz, Chava Biederman, Beila Englander, Israel
Fishman, Judith Fried, Malka Friedman, Chanie Fulop, Rachel
Guttman, Simon Josef, Baila Klein, Malky Roth-Tabak,

Plaintiffs-Petitioners,

-against-

Index No. 156722/2020

Department of Health and Mental Hygiene of the City Of New
York,

Edmead, J.
IAS 35

Defendant-Respondent.

----- X

**REPLY MEMORANDUM OF LAW IN
FURTHER SUPPORT OF RESPONDENT
DOHMH’S CROSS-MOTION TO DISMISS**

PRELIMINARY STATEMENT

Plaintiffs-Petitioners (hereinafter “petitioners”) are ten parents of ten children who were not vaccinated against measles at the time of a measles epidemic in the area where they lived, the Williamsburg area of Brooklyn.¹ They commenced the instant Article 78 proceeding, styled also as a “declaratory judgment petition,” challenging the public health efforts of defendant-respondent the New York City Department of Health and Mental Hygiene (hereinafter “respondent” or “DOHMH”), to quell the 2019 epidemic by persuading an increase in that area in the rate of measles vaccination by use of the MMR vaccine.

¹ Petitioners’ counsel notified the Court that the eleventh petitioner, Judith Fried, wished to withdraw from the case, and that withdrawal was effectuated by Order of this Court dated February 8, 2021 (NYSCEF Doc. No. 86).

Reply Memorandum in Further Support of
Respondent DOHMH’s Cross-Motion to Dismiss

Petitioners have asked this Court to vacate the civil summonses issued by DOHMH for violation of a DOHMH Order and subsequent Resolution of the Board of Health continuing that Order mandating the administration of the MMR vaccine to their children, with a civil penalty as the consequence for non-compliance. These summonses were adjudicated at the New York City Office of Administrative Trials and Hearings (“OATH”). An OATH Hearing Officer found each of the petitioners in violation for having failed to have certain of their children vaccinated against measles, and imposed the \$1,000 civil penalty set forth by DOHMH, which determinations were upheld by the OATH Appeals Unit.

Petitioners seek a declaratory judgment that DOHMH’s Order and the Board of Health Resolution mandating the administration of the vaccine or else be assessed a civil penalty after an administrative hearing violated their constitutional rights. They also allege that respondent “acted arbitrarily, capriciously, and contrary to law in rendering the determinations they challenge.” The allegation that the determinations were rendered by respondent DOHMH is erroneous. The determinations were in fact rendered by an OATH Hearing Officer and the OATH Appeals Unit. Petitioners ask this Court to vacate the OATH determinations, even though they failed to name OATH as a party herein. They also seek an award of attorney’s fees, costs, and disbursements pursuant to 42 USC § 1983 and CPLR 8101.

All of petitioners’ arguments fail for the reason set forth in the Memorandum of Law submitted in support of DOHMH’s pending cross-motion to dismiss the petition (“DOHMH’s Memo,” NYSCEF Doc. No. 80). The instant reply memorandum responds to the petitioners’ arguments in opposition as is set forth in their “Reply in Further Support of the Verified Article 78 and Declaratory Judgment Petition & Opposition to Defendant’s Cross-Motion to Dismiss” (“Ps’ Opp.,” NYSCEF Doc. No. 89).

Reply Memorandum in Further Support of
Respondent DOHMH’s Cross-Motion to Dismiss

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STATEMENT OF FACTS AND APPLICABLE LAW

Respondent respectfully refers the Court to the Affirmation of Louise Moed, dated January 4, 2021 (NYSCEF Doc. No. 62); the exhibits annexed thereto, in particular, the affirmation of DOHMH Dr. Demetre Daskalakis, Deputy Commissioner of DOHMH's Division of Disease Control that was submitted in the 2019 matter of *C.F. v. DOHMH*, 191 AD3d 52 (2d Dep't 2020) (hereinafter the "Daskalakis Aff.," NYSCEF Doc. No. 63); and respondent DOHMH's Memorandum of Law dated January 4, 2021 (NYSCEF Doc. No. 80).²

ARGUMENT

POINT I

THE DOHMH COMMISSIONER'S ORDER AND SUBSEQUENT BOARD OF HEALTH RESOLUTION WERE RATIONALLY BASED ON NATIONALLY ACCEPTED MEDICAL STANDARDS.

Petitioners reiterate their reliance on the "unrebutted" medical papers they submitted into evidence at the administrative hearings at OATH (Ps' Opp. ¶¶ 7-18). It is true that DOHMH did not attempt to rebut these papers. The safety and efficacy of the MMR vaccine is within the authority and expertise of the United States Centers for Disease Control (the "CDC"). It was therefore rational for DOHMH to attempt to increase MMR vaccination during a measles epidemic and for OATH to credit DOHMH's statements regarding the safety and

² Petitioners allege that the Moed Affirmation "mischaracterizes portions of the OATH hearing" (P's Opp. at p1, n1). Petitioners point to the unofficial transcript of the Tabak hearing that they submitted as Exhibit D to the petition, the hearing at which petitioners submitted numerous medical papers challenging the safety and efficacy of the MMR vaccine. The official transcript of the Tabak hearing by OATH's reporting service is annexed to DOHMH's cross-motion to dismiss as Exhibit 5. All references in DOHMH's cross-motion are to this official transcript.

efficacy of the MMR vaccine without DOHMH having to rebut the medical papers submitted by petitioners at their OATH hearings. See a full discussion of this issue in DOHMH's Memo Point I (PDF pp 11-16).

Petitioners object (Ps' Opp. ¶¶ 11-17) to the inclusion of the Daskalakis Affidavit (Exhibit 1 to the Moed Aff., NYSCEF Doc. No. 63) in support of DOHMH's cross-motion to dismiss. Because DOHMH is following the nationally accepted medical standards regarding the MMR vaccine, it was appropriate to include the Daskalakis Affidavit in DOHMH's cross-motion to dismiss so as to apprise this Court of these medical standards. The pending cross-motion to dismiss the pending Article 78 proceeding does not require that DOHMH present or restrict itself to the administrative record. In fact, the DOHMH does not have to *prove* the safety and efficacy of the MMR vaccine at each and every OATH hearing concerning that vaccine. The Daskalakis Affidavit sets before this Court the nationally accepted medical standards.

A challenge similar to petitioners' challenge herein to the safety and efficacy of the MMR vaccine was rejected in the recent decision handed down by the Appellate Division in *C.F. v. NYC Department of Health and Mental Hygiene*, 191 AD3d 52 (2d Dep't 2020). See DOHMH's Memo at PDF pp 13-14.

POINT II

THE ORDER AND THE BOARD OF HEALTH RESOLUTION WERE COMPLETELY CONSISTENT, AND THE DIFFERENCES BETWEEN THEM WERE *DE MINIMUS* AND OF NO MOMENT WITH RESPECT TO PETITIONERS.

The Commissioner's Order and the Board of Health Resolution were completely consistent in addressing the measles epidemic in Williamsburg, and the differences between

Reply Memorandum in Further Support of
Respondent DOHMH's Cross-Motion to Dismiss

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them were *de minimus* and of no moment with respect to petitioners. See DOHMH's Memo at PDF p 22.

Petitioners assert that the Board of Health was constrained to either "continue or rescind" the Order issued by the DOHMH Commissioner in emergency circumstances, such as the Williamsburg measles epidemic at issue herein (Ps' Opp. ¶ 4). Petitioners' extremely narrow interpretation of those terms, if given credence, would prevent the Board of Health from fashioning an appropriate Resolution to address a health emergency. The amendments made by the Board of Health to the Commissioner's Order refined that Order, which had also been issued in an emergency situation. For example, the Resolution made clear that the MMR vaccination mandate would not be enforced by way of criminal fines, even though the Order included the boilerplate included in most DOHMH Orders pointing to the availability of criminal fines for violations of the Health Code. See Moed Aff. ¶¶ 16-18 and DOHMH's Memo at PDF p 22.

A paragraph-by-paragraph comparison of the language of the Order and the language of the Resolution (Exhibits 2 and 3) makes clear that the MMR vaccination requirements of the Order were explicitly continued by the Resolution. A mechanical interpretation of the terms "continue or rescind" to prohibit refinement of the requirements by the Board of Health would undermine the Board's crucial role in protecting the public health.

Petitioners reiterate their challenge to the viability of the Order on the day the first summons was issued (Ps' Memo at ¶¶ 5-6). This issue is discussed in detail in in DOHMH's Memo at 20.

POINT III**NEITHER THE ORDER NOR THE RESOLUTION VIOLATED ANY FEDERAL OR STATE CONSTITUTIONAL RIGHTS IN THAT THEY DID NOT MANDATE THE FORCIBLE ADMINISTRATION OF THE MMR VACCINE TO PETITIONERS' CHILDREN.**

Petitioners reiterate their claim that requiring the injection of the MMR vaccine into their children violated their rights under the United States and New York State Constitutions (Ps' Opp. ¶ 19). Petitioners ignore the fact that neither the Commissioner's Order nor the Board of Health Resolution mandated the forcible administration of the MMR vaccine to their children. See DOHMH's Memo at PDF pp 23-24.

Because the Order and Resolution violated no constitutional right, no attorneys' fees can be awarded to petitioners pursuant to 42 USC § 1983, which fees petitioners again request in their opposition at p 11.

CONCLUSION

Petitioners have failed to establish the lack of a rational basis for the OATH determinations that they were in violation of the DOHMH Order and Board of Health Resolution. They have conceded in paragraph 6 of their petition that they *were* in violation, and they failed at OATH to provide any valid defense for any of the subject children either being immune to measles or needing a medical exemption as attested to by a medical professional. See DOHMH's Memo Point I(A) and (B), PDF pp 16-21. The petitioners have failed to show that the Order and Resolution lacked a rational basis, as those two orders were in conformance with the national medical standards for preventing and addressing a measles epidemic. Finally, they also failed to show that the issuance of the summonses violated their constitutional rights, as

Reply Memorandum in Further Support of
Respondent DOHMH's Cross-Motion to Dismiss

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no forcible vaccination was ordered by DOHMH. *See* DOHMH's Memo Point III, PDF pp 23-24.

For the foregoing reasons, the petition should be denied and the instant proceeding dismissed in its entirety.

Dated: New York, New York
April 28, 2021

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CERTIFICATION UNDER UNIFORM CIVIL RULE 202.8-b

Pursuant to Rule 202.8-b(c) of the Uniform Civil Rules for the Supreme Court and the County Court, I hereby certify as follows: according to Microsoft Word, the portions of the annexed Reply Memorandum that must be included in a word count contain 1,429 words, and thus this document complies with the word count limit set forth in Uniform Civil Rule 202.8-b(a).

Dated: New York, New York
April 28, 2021


LOUISE MOED