Informed Consent Action Network

July 31, 2018

VIA FEDERAL EXPRESS

Nancy Bennett, MD, MS
Professor of Medicine and Public Health Sciences
Director, Center for Community Health
Co-director, Clinical and Translational Science Institute
University of Rochester School of Medicine and Dentistry
601 Elmwood Avenue
Box 614
Rochester, NY 14642

Re: *Efficacy of the mumps vaccine*

Dear Dr. Bennett,

Thank you for the opportunity to speak regarding the efficacy of the mumps vaccine at the Advisory Committee on Immunization Practices ("ACIP") meeting held on June 20, 2018. As a follow-up to that comment, attached is information concerning a civil lawsuit filed against Merck & Co. ("Merck") that every member of ACIP should be aware of when considering the efficacy of the mumps vaccine.

Attached as **Exhibit A** is a copy of the Amended Complaint in *United States of America et al. v. Merck & Co., Inc.*, Case No. 10-4373, dated April 27, 2012, filed in Federal Court. In that document, the plaintiffs, the United States of America and two former Merck virologists, describe "Merck's efforts for more than a decade to defraud the United States through Merck's ongoing scheme to sell the government a mumps vaccine that is … falsely certified as having an efficacy rate that is significantly higher than it actually is." (Ex. A ¶ 1.)

As detailed in the Amended Complaint, Merck obtained a license for its mumps vaccine in 1967 and is the only company to ever obtain a license for a mumps vaccine in the United States. (Ex. A ¶ 16.) In the late 1990s, in order to obtain approval for ProQuad in the U.S. and Europe, Merck needed to reconfirm its claims of efficacy for its mumps vaccine made thirty years prior. (Ex. A. ¶ 22.) Merck's virologists working on testing the efficacy of the mumps vaccine revealed that after Merck could not demonstrate a 95 percent efficacy for its mumps vaccine, the results were simply fraudulently falsified to achieve this result. (Ex. A ¶¶ 15-131.)

As explained by Merck's virologists, Merck took blood samples pre-vaccinated with the mumps vaccine and then exposed them to the mumps virus. (Ex. A ¶¶ 25-28.) When a test against a live strain of mumps would not yield a 95 percent efficacy, Merck tried to improperly obtain this

rate using an attenuated strain of the mumps virus. (Ex. A ¶¶ 29-30.) When this *still* would not achieve 95 percent efficacy, Merck tried different virus dilutions, different straining procedure, and even more liberal antibody counting techniques. (Ex. A ¶¶ 31-32.) The Merck lab even improperly added animal antibodies to the blood samples and still could not achieve a 95 percent efficacy rate. (Ex. A ¶¶ 33-39.) When it was clear that even improper testing techniques could not produce the desired result, the test reports were simply falsified. (Ex. A ¶¶ 40-51.) According to the Merck virologists, to document the desired efficacy rate, Merck destroyed result sheets and falsified various documents. (*Id*.) The Merck virologists claim this fraud was done with the direct authority and approval of Merck's senior management. (Ex. A ¶¶ 52-58.)

Attached as **Exhibit B** is a copy of the Amended Memorandum and Order of the Court, dated September 5, 2014, denying Merck & Co.'s motion to dismiss the Amended Complaint.

Attached as **Exhibit C** is a copy of the Docket Report, dated July 13, 2018, for this lawsuit which reflects that Merck & Co. has filed every document related to the mumps efficacy under seal – see yellow highlighting. It is respectfully suggested that ACIP request copies of these documents so that it can directly further assess the actual efficacy rate of the mumps vaccine. Understanding same would appear critical to ACIP's mission.

We hope that you find this information useful in considering the efficacy of the mumps vaccine and thank you for your consideration of the enclosed material.

Very truly yours,

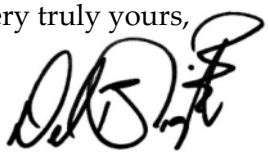

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Exhibit A

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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America *ex rel.*,

Stephen A. Krahling and Joan A. Wlochowski,

Plaintiffs,

v.

Merck & Co., Inc.

Defendant.

Civil Action No. 10-4374 (CDJ)

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

JURY TRIAL DEMANDED

Stephen Krahling and Joan Wlochowski bring this *qui tam* action as Relators on behalf of the United States against their former employer, Merck & Co., Inc. ("Merck"), under the False Claims Act, 31 U.S.C. §§ 3729-3733, and allege -- upon knowledge with respect to their own acts and those they personally witnessed, and upon information and belief with respect to all other matters -- as follows:

INTRODUCTION

1. This case is about Merck's efforts for more than a decade to defraud the United States through Merck's ongoing scheme to sell the government a mumps vaccine that is mislabeled, misbranded, adulterated and falsely certified as having an efficacy rate that is significantly higher than it actually is.

2. Specifically, in an effort to maintain its exclusive license to sell the vaccine and its monopoly of the U.S. market for mumps vaccine, Merck has fraudulently represented and continues to falsely represent in its labeling and elsewhere that its mumps vaccine has an

efficacy rate of 95 percent or higher. This is the efficacy rate on which Merck's original government approval for the vaccine was based more than forty years ago. In truth, Merck knows and has taken affirmative steps to conceal -- such as by using improper testing techniques, falsifying test data in a clinical trial, and violating multiple duties of government disclosure -- that the efficacy rate of Merck's mumps vaccine is, and has been since at least 1999, significantly lower than this 95 percent rate.

3. Relators Krahling and Wlochowski were employed as virologists in the Merck lab that performed this fraudulent efficacy testing. They witnessed firsthand the improper testing and data falsification in which Merck engaged to conceal what Merck knew about the vaccine's diminished efficacy. In fact, their Merck superiors and senior Merck management pressured them to participate in the fraud and subsequent cover-up when Relators objected to and tried to stop it.

4. As a result of Merck's fraudulent scheme, the United States has over the last decade paid Merck hundreds of millions of dollars for a vaccine that does not provide the efficacy Merck claims it provides and does not provide the public with adequate immunization. Had Merck complied with its multiple duties of disclosure and reported what it knew of the vaccine's diminished efficacy -- rather than engage in fraud and concealment -- that information would have affected (or surely had the potential to affect, which is all the law requires) the government's decision to purchase the vaccine. However, since the government was not fully informed, it did not have the opportunity to consider its options, including not purchasing the vaccine from Merck, paying less, requiring a labeling change, requiring additional testing, or prioritizing development and approval of a new vaccine from Merck or another manufacturer.

5. Merck's failure to disclose what it knew about the diminished efficacy of its mumps vaccine has caused the government to purchase mislabeled, misbranded, adulterated and falsely certified vaccines in violation of Merck's contract with the Centers for Disease Control ("CDC") and in violation of the law.

6. As the single largest purchaser of childhood vaccines (accounting for more than 50 percent of all vaccine purchases), the United States is by far the largest financial victim of Merck's fraud. But the ultimate victims here are the millions of children who every year are being injected with a mumps vaccine that is not providing them with an adequate level of protection against mumps. And while this is a disease the CDC targeted to eradicate by now, the failure in Merck's vaccine has allowed this disease to linger with significant outbreaks continuing to occur.

7. Relators bring this case on behalf of the United States to recover the funds that the government spent for this fraudulently mislabeled, misbranded, adulterated and falsely certified vaccine, and for all associated penalties. They also bring this case to stop Merck from continuing with its scheme to misrepresent the true efficacy of its mumps vaccine and require Merck to comply with its reporting, labeling and testing obligations under its contract with the CDC and under this country's vaccine regulatory regime.

PARTIES

8. Relator Stephen A. Krahling is a citizen of the United States and a resident of Pennsylvania. He was employed by Merck from 1999 to 2001 as a virologist in Merck's vaccine division located in West Point, Pennsylvania. During his employment at Merck, Krahling witnessed firsthand, and was asked to directly participate in, fraud in a clinical trial relating to

the efficacy of Merck's mumps vaccine.

9. Relator Joan Wlochowski is a citizen of the United States and a resident of Connecticut. She was employed by Merck from January 2001 to August 2002 as a virologist in Merck's vaccine division in West Point, Pennsylvania. During her employment there, Wlochowski also witnessed firsthand, and was asked to directly participate in, fraud in a clinical trial relating to the efficacy of Merck's mumps vaccine.

10. Defendant Merck is headquartered in New Jersey with its vaccine division based in West Point, Pennsylvania. Merck is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. Merck is also a leading seller of childhood vaccines and currently markets in the U.S. vaccines for 12 of the 17 diseases for which the CDC currently recommends vaccination.

11. Merck is the sole manufacturer licensed by the Food and Drug Administration ("FDA") to sell mumps vaccine in the United States. Merck's mumps vaccine, together with Merck's vaccines against measles and rubella are sold as MMRII. Merck annually sells more than 7.6 million doses of the vaccine in the U.S. for which it derives hundreds of millions of dollars of revenue. The U.S. purchases approximately 4 million of these doses annually. Merck also has a license in the U.S. to sell ProQuad, a quadravalent vaccine containing MMRII vaccine and chickenpox vaccine. Under a license from the European Medicines Agency ("EMA"), Merck also sells mumps vaccine in Europe as a part of the trivalent MMRVaxpro and the quadravelent ProQuad through Sanofi Pasteur MSD, a joint venture with the vaccine division of the Sanofi Aventis Group. ProQuad has been sold intermittently in the U.S. and Europe from its approval in 2005 until 2010.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a).

13. This Court has personal jurisdiction over Merck under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because a substantial part of the events giving rise to this Complaint occurred in this District. Indeed, Merck's fraudulent scheme with respect to its mumps vaccine was originated and continues to be carried out in this District at Merck's vaccine division facility in West Point, Pennsylvania.

14. Pursuant to 31 U.S.C. § 3732(a), venue is proper because Merck can be found in and transacts business within this District. Throughout the time period relevant to the allegations of this Complaint, Merck engaged in substantial business transactions within this District and committed many of the violations proscribed by 31 U.S.C. § 3729 in this District.

BACKGROUND

15. For more than forty years, Merck has had a de-facto exclusive license from the federal government to manufacture and sell a mumps vaccine in the U.S.

16. Merck first obtained approval for the vaccine in 1967 from the Department of Biologics Standards of the National Institute of Health ("DBS"), the agency at the time responsible for licensing vaccines. The vaccine was developed by Dr. Maurice Hilleman, at Merck's West Point research facility, from the mumps virus that infected his five year-old daughter Jeryl Lynn. Merck continues to use this "Jeryl Lynn" strain of the virus for its vaccine today.

17. Merck's original mumps vaccine was delivered to patients in a single, stand-alone injection called Mumpsvax. In 1971, Merck developed a combination vaccine which delivered Merck's vaccines for measles, mumps and rubella ("MMR") together in one injection. The same year, Merck obtained DBS approval to manufacture and sell MMR vaccine. In 1978, Merck obtained approval from the FDA (which succeeded the DBS as the agency responsible for licensing vaccines) for the manufacture and sale of MMRII, a replacement for MMR containing a different strain of the rubella virus. Since that time, Merck has sold more than 450 million doses of MMRII world-wide, with approximately 200 million doses sold in the U.S.

18. In September 2005, Merck obtained FDA approval for ProQuad.[1] Merck sold ProQuad in the U.S. from its approval in 2005 until June, 2007. According to Merck, the vaccine became unavailable because of certain manufacturing constraints. The vaccine was briefly available again in 2010 but has not been available since then.

19. In order to obtain its original government approval to sell its mumps vaccine, Merck conducted field studies of vaccinated children and concluded that the vaccine had an efficacy rate of 95 percent or higher. This meant that 95 percent of those given the vaccine were considered immunized against mumps. This is important because when an adequate number of people have immunity, the chances of an outbreak are reduced, and -- ultimately -- eliminated. If there is insufficient immunity, a real risk of continued disease outbreaks exists. When mumps outbreaks occur in vaccinated populations, it afflicts older children who are at greater risk of serious complications.

[1] Mumps vaccine used herein refers to any of Merck's vaccines containing a mumps component such as MMR, MMRII and ProQuad.

20. Before the introduction of the vaccine, there were approximately 200,000 cases of mumps in the U.S. annually. This number dropped off precipitously after the widespread administration of Merck's vaccine. The CDC projected that, by 2010, mumps could be completely eradicated. Unfortunately, that has not happened. Beginning in 2006, there has been a resurgence in mumps outbreaks.

21. Merck predicted the resurgence of outbreaks given the diminished effectiveness of its mumps vaccine. While Merck obtained its original license in 1967 stating that its vaccine was at least 95 percent effective, Merck knows that the vaccine's efficacy is significantly less than that now. Merck knows that the continued passaging of the attenuated virus to make more vaccine for distribution has altered the virus and has degraded the efficacy of the product.

22. Rather than develop a new mumps vaccine with greater efficacy, or permit other manufacturers to enter the U.S. market with a competing vaccine, Merck has instead taken pains to preserve its exclusive U.S. license by maintaining before the government and the public that its more than forty-year old vaccine continues to have an efficacy rate of 95 percent or higher. This was easy to do for a while because Merck was able to refer back to the efficacy testing it conducted in connection with the government's original granting of Merck's license to sell the mumps vaccine. However, beginning in the late 1990s, Merck initiated new efficacy testing of its mumps vaccine. This testing coincided with an application to change the MMRII labeling in the U.S. and an application for a license to sell MMRII in Europe. This testing also coincided with Merck's development and quest for approval of ProQuad in both the U.S. and Europe.

23. Without demonstrating that its mumps vaccine continued to be 95 percent effective, Merck risked losing the monopoly it had over the sale of mumps vaccine in the U.S.

With respect to MMRII or Mumpsvax, the government might have negotiated to pay less for the vaccine, required a labeling change, or required additional testing. Or, the government might have stopped purchasing Merck's vaccine altogether as the door would be open to new manufacturers to enter the market. With respect to ProQuad, the government might not have approved the vaccine at all. Under any of these scenarios, Merck risked losing hundreds of millions of dollars in revenue from this very profitable enterprise.

24. So, Merck set out to conduct testing of its mumps vaccine that would support its original efficacy finding. In performing this testing, Merck's objective was to report efficacy of 95 percent or higher regardless of the vaccine's true efficacy. The only way Merck could accomplish this was through manipulating its testing procedures and falsifying the test results. Relators Krahling and Wlochowski participated on the Merck team that conducted this testing and witnessed firsthand the fraud in which Merck engaged to reach its desired results. Merck internally referred to the testing as Protocol 007.

MERCK'S FRAUD IN TESTING THE EFFICACY OF ITS MUMPS VACCINE

A. Merck's Abandonment of Its Original PRN Test and Test Results

25. The original methodology Merck employed under Protocol 007 was a Mumps Plaque Reduction Neutralization ("PRN") Assay. Preliminary testing commenced in 1999 at Merck's West Point facility and was led by Senior Investigator David Krah and his second in command, Mary Yagodich. Merck's Executive Director of Vaccine Research, Alan Shaw, approved the testing methodology Krah and Yagodich employed. Relator Krahling witnessed Krah and Yagodich as they conducted the preliminary testing.

26. As the name of the test indicates, the PRN test measures the virus neutralization that occurs after administration of the mumps vaccine. Merck's test was in some measure similar to the testing procedure regarded in the scientific community as the "gold standard" for testing how well a vaccine works. Blood samples are taken from children both before they receive the vaccine and again after they have been injected with the vaccine (after sufficient time has passed for the vaccine to produce an immune response). The paired blood samples are then individually incubated with the target virus and added to sheets of cells. Where the virus replicates in the cell sheet it leaves a plaque, or hole.

27. The pre-vaccinated child will not typically have immunity to the disease. Therefore, the pre-vaccinated blood will be unable to neutralize the virus and plaques will form where the virus has infected the cells. In contrast, if the vaccine has stimulated the child's immune system to develop antibodies against the virus, the post-vaccinated blood will neutralize the virus. The post-vaccinated blood sample will consequently show a smaller number of plaques, or holes, in the cell sheet compared to the pre-vaccinated sample.

28. A PRN test simply compares virus growth in the presence of the pre- and post-vaccinated blood samples. The number of plaques (where the virus has grown) is compared to determine if the vaccine caused the child to develop a sufficient level of antibodies to neutralize the virus. Results are reported in terms of seroconversion. A seroconversion occurs when the pre-vaccination blood sample is "negative" (meaning, insufficient antibodies to neutralize the virus) and the post-vaccination sample is "positive" (meaning, sufficient antibodies to neutralize the virus). Seroconversion occurs, therefore, when a blood sample goes from "pre-negative" (insufficient antibodies) to "post-positive" (sufficient antibodies). Seroconversion in the lab is

the best correlate for efficacy -- how the vaccine works at successfully immunizing children. For the purposes of its testing, Merck was looking for a seroconversion rate of 95 percent or higher to support its original efficacy finding and the efficacy it continued to represent in its labeling.

29. While Merck's PRN test was modeled after the neutralizing test generally accepted in the industry, it diverged from this "gold standard" test in a significant way. It did not test the vaccine for its ability to protect against a wild-type mumps virus. A wild-type virus is a disease-causing virus, a strain of the virus as it exists in nature and would confront a person in the real world. That is the type of real-life virus against which vaccines are generally tested. Instead, Merck tested the children's blood for its capacity to neutralize the attenuated Jeryl Lynn virus. This was the same mumps strain with which the children were vaccinated. The use of the attenuated Jeryl Lynn strain, as opposed to a virulent wild-type strain, subverted the fundamental purpose of the PRN test which was to measure the vaccine's ability to provide protection against a disease-causing mumps virus that a child would actually face in real life. The end result of this deviation from the accepted PRN gold standard test was that Merck's test overstated the vaccine's effectiveness.

30. Even with a deviation that could only overstate how well the vaccine worked, the results from Merck's preliminary testing (which involved testing blood samples of approximately 60-100 children) yielded seroconversion rates significantly below the desired 95 percent threshold. Krah admitted as much to Relator Krahling. He also admitted that the efficacy of Merck's vaccine had declined over time, explaining that the constant passaging of virus to make

more vaccine for distribution had degraded the product and that because of this, mumps outbreaks would increase over time.

31. Krah further admitted to Krahling that he and Yagodich tried numerous other, often undocumented, techniques to modify the PRN test in order to improve the seroconversion results they could measure, including trying different virus dilutions, different staining procedures and even counting plaques more liberally. These other techniques -- like using the vaccine strain rather than the wild-type strain of the virus -- subverted the purpose of the PRN test. In the end, however, none of it mattered. Merck had to abandon its methodology because no matter how Krah and Yagodich manipulated the procedures, they could not reach the 95 percent seroconversion threshold.

32. So, Merck abandoned the PRN methodology that yielded unsatisfactory results and worked towards developing a new, rigged methodology that would allow Merck to report its desired seroconversion results.

B. Merck's Improper Use of Animal Antibodies In Its "Enhanced" PRN Test

33. The new methodology Merck devised and ultimately used to perform the mumps efficacy testing under Protocol 007 was an Enhanced Mumps Plaque Reduction Neutralization Assay. It was again led by Krah and approved by Shaw and commenced in 2000. Relators Krahling and Wlochowski participated on the team that conducted the testing using this supposedly enhanced methodology. Each of them witnessed firsthand the falsification of the test data in which Merck engaged to reach its 95 percent seroconversion threshold. In fact, each was significantly pressured by Krah and other senior Merck personnel to participate in this fraud.

34. From the outset, Merck's objective with this "enhanced" procedure was clear. It was not to measure the actual seroconversion rate of Merck's mumps vaccine. It was to come up with a methodology that would yield a minimum 95 percent seroconversion rate regardless of the vaccine's true efficacy. The very first page of an October 2000 Merck presentation on the "enhanced" methodology stated just that:

> **Objective:** Identify a mumps neutralization assay format . . . that permits measurement of a ≥ 95% seroconversion rate in MMR®II vaccinees.

Notably, nowhere in this presentation did Merck provide any kind of justification or explanation for abandoning its original PRN methodology and the unsatisfactory seroconversion results it yielded.

35. To reach the stated objective for its "enhanced" test and increase the measured seroconversion rate to the predetermined 95 percent threshold, Merck continued to use its scientifically flawed PRN methodology -- that tested against the vaccine strain rather than the wild-type strain -- but with one additional material change. Merck added animal antibodies to both the pre and post-vaccination blood samples. The use of animal antibodies in laboratory testing is not uncommon. They can serve as a highlighter of sorts to identify and count human antibodies that otherwise might not be identifiable on their own. When used in that way, animal antibodies make it easier to see the human antibodies. They do not alter what is being measured. However, Merck added animal antibodies for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the lab.

36. In a laboratory setting, animal antibodies can combine with human antibodies to cause virus neutralization that would not otherwise occur from the human antibodies alone.

Merck's "enhanced" methodology permitted various types of human antibodies to be counted as mumps neutralizing antibodies when it was actually the animal antibodies combining with those human antibodies causing the neutralization. Merck also did not apply a proper "control" to isolate whether virus neutralization was caused by the human antibodies alone or in combination with the animal antibodies. Rather, Merck included in its seroconversion measure all virus neutralizations regardless of whether they resulted from human antibodies or by their combination with the animal antibodies. This "enhanced" PRN methodology thereby allowed Merck to increase dramatically the recordable instances of mumps virus neutralization and to count those neutralizations toward seroconversion and its measure of the vaccine's success.

37. Merck knew that the neutralizations attributable to the animal antibodies would never exist in the real world. This is because the human immune system, even with the immunity boost provided by an effective vaccine, could never produce animal antibodies. And adding this external factor as a supplement to a vaccine was not an option because it could result in serious complications to a human, even death. Thus, the "uncontrolled" boost to neutralization Merck designed using these animal antibodies in its laboratory did not in any way correspond to, correlate with, or represent real-life (*in vivo*) virus neutralization in vaccinated people.

38. But the use of the animal antibodies allowed Merck to achieve its high seroconversion objectives. In fact, paired blood samples that were found under Merck's 1999 PRN methodology to lack sufficient virus neutralizing antibodies were now considered seroconverted using the "enhanced" methodology. Indeed, in one panel of sixty paired blood samples, Merck measured a seroconversion rate of 100 percent. In other words, non-neutralizing

concentrations of antibodies that would never protect a child from mumps in the real world were, under Merck's "enhanced" methodology, treated as vaccine successful solely because of the additional neutralization provided by the animal antibodies.

39. Krah defended the use of the animal antibodies in the "enhanced" PRN test by pointing to the FDA's purported approval of the process. However, whatever FDA approval Merck may have received for this testing, the FDA was not fully aware of the extent of Merck's manipulation of the testing, including Merck's wholesale fabrication of test data to reach its preordained 95 percent efficacy threshold.

C. Merck's Falsification of the "Enhanced" PRN Test Results

40. There was one significant problem with Merck's improper use of the animal antibodies to boost its virus neutralization counts which would be evident to any scientist reviewing the test data. The animal antibodies boosted neutralization counts not only in the post-vaccination blood samples. They also boosted neutralization counts in the pre-vaccination samples. However, too much virus neutralization in the pre-vaccinated sample created a "pre-positive," which means enough virus neutralization to characterize the child as immune without the vaccine.

41. Pre-positives ordinarily occur in a small percentage of the child population that is immune to mumps even without vaccination. This immunity would principally come from a previous exposure to the mumps virus, or from immunity transferred to a child from the mother *in utero*. However, the incidence of this immunity is small, generally measured by the scientific community at around 10 percent of the child population.

42. The problem for Merck was that with the addition of the animal antibodies to the pre-vaccination blood samples it was seeing a significantly higher percentage of pre-positives than the 10 percent industry recognized occurrence of such immunity. In the results of one test that Relators Krahling and Wlochowski both witnessed in the summer of 2001, the pre-positive rate was more than 80 percent. Krah instructed Wlochowski to throw out the results and the actual experimental plates of that particular test thereby destroying all traces of the unwanted results.

43. The existence of such a high percentage of pre-positives threatened the viability of Merck's "enhanced" methodology. As a practical matter, with a pre-positive, any favorable results in the post-vaccinated sample could not be counted as a vaccine success toward the 95 percent efficacy target. A sample appearing positive before the vaccine, and staying positive after the vaccine, was not a seroconversion.

44. Just as important, the high pre-positive rate would red flag the methodology as flawed. The FDA would question the results of a test that had such a high level of pre-positives. Krah stated this explicitly to the members of his lab, including Relators Krahling and Wlochowski. If Merck wanted to keep the artificial boost in post-vaccination positives provided by the animal antibodies, it would have to eliminate the associated boost in pre-vaccination positives.

45. In the October 2000 presentation, Merck acknowledged that its initial "enhanced" PRN testing results yielded a level of pre-positives that was too high. Merck also made clear that it needed to "optimize" the amount of animal antibodies used in the process so that the testing would yield a pre-positive rate of 10 percent or less and a seroconversion rate of 95 percent or

more: "Pre-positive rate is higher than desirable," and "Continue evaluation of results using optimized [animal antibodies] amount (target < 10% pre-positive rate and ≥ 95% seroconversions)."

46. The problem was that no amount of tinkering with the amount of animal antibodies added would produce a pre and post-vaccination virus neutralization for Merck's vaccine within the desired range. Without the animal antibodies, Merck could not support a sufficient level of post-vaccination neutralization. Conversely, by adding the animal antibodies, Merck could not avoid having too high a level of pre-vaccination neutralization (*i.e.*, too many pre-positives). This left only one way for Merck to reach its desired seroconversion outcome -- falsify the test results.

47. Specifically, Krah and Yagodich and other members of Krah's staff falsified the test results to ensure a pre-positive neutralization rate of below 10 percent. They did this by fabricating their plaque counts on the pre-vaccination blood samples, counting plaques that were not actually there. With these inflated plaque counts, Merck was able to count as pre-negative those blood samples that otherwise would have been counted as pre-positive because of the increased neutralization caused by the animal antibodies.

48. Merck's falsification of the pre-vaccination plaque counts was performed in a broad-based and systematic manner from December 2000 until at least August 2001:

- Krah stressed to his staff that that the high number of pre-positives they were finding was a problem that needed to be fixed.
- Krah directed his staff to re-check any sample found to be pre-positive to see if more plaques could be found to convert the sample to a pre-negative.

- Krah and Yagodich falsified plaque counts to convert pre-positives to pre-negatives, and directed other staff scientists to do the same.

- Krah appointed Yagodich and two others to "audit" the testing that other staff scientists had performed. These audits were limited to finding additional plaques on pre-positive samples thereby rendering them pre-negatives.

- Krah instituted several measures to isolate the pre-positive samples, facilitate their "re-count" and consequent conversion to pre-negatives. For example, when manually changing original counting sheets proved too time-consuming, Krah employed an excel spreadsheet which would automatically highlight the undesirable pre-positives so that they could be targeted more efficiently. The data was entered, highlighted and changed before it was ever saved.

- Krah also engaged in the destruction of evidence to minimize the chances of detection. He not only employed the excel spreadsheet which left no paper trail. He also destroyed test results, substituted original counting sheets with "clean" sheets, and ordered the staff in the lab to do the same.

- Merck cancelled (in March 2001) a planned outsource of the testing to a lab in Ohio because the outside lab was unable to replicate the seroconversion results Krah was obtaining in his lab. Krah and his staff conducted all the remaining testing instead.

49. Unsurprisingly, none of the "recounting" and "retesting" that Krah and his staff performed as part of the "enhanced" testing was performed on any post-vaccination samples or on any pre-vaccination samples that were pre-negative. This additional "rigor" was only applied to the pre-positive samples, the very samples Merck had identified as undesirable and which kept Merck from attaining its target of $\leq$ 10% pre-positive rate and $\geq$ 95% seroconversion.

50. Relators Krahling and Wlochowski engaged in numerous efforts to stop the fraud. They questioned and complained to Krah about the methodology being employed, particularly the manipulation of pre-positive data. They attempted to dissuade others from participating. They initiated numerous calls to the FDA to expose the fraud. And they attempted to document the fraud, even as evidence of it was being destroyed. But Relators' efforts were to no avail. For

every effort they took to stop the fraud, Merck adapted the scheme to assure the falsification continued. For example, when Relators objected to changing their own plaque counts, Krah appointed other staff, as so-called auditors, willing to falsify the data.

51. In July 2001, Relators Krahling and Wlochowski secretly conducted their own audit of the test results to confirm statistically the fraud that was occurring with the "enhanced" testing. They reviewed approximately 20 percent of the data that Merck had collected as part of the "enhanced" test. In this sampling, they found that 45 percent of the pre-positive data had been altered to make it pre-negative. No pre-negatives were changed to pre-positives. No post-positives were changed to post-negatives. No post-negatives were changed to post-positives. All changes were in one direction -- reducing the incidence of pre-positives. The statistical probability of so many changes occurring in just the pre-positive data and in no other data was more than a trillion to one. And that is a conservative measure given the likelihood that an even greater number of pre-positives were changed but remained undetected because the changes were not recorded in Merck's files.

D. The Complicity of Merck's Senior Management

52. Krah did not act alone in orchestrating the falsification of the "enhanced" PRN test results. He acted with the authority and approval of Merck's senior management.

53. For example, in April 2001, after Merck cancelled the planned outsourcing of the remainder of the mumps efficacy testing, Emilio Emini, the Vice President of Merck's Vaccine Research Division, held a meeting with Krah and his staff, including Relators Krahling and Wlochowski. Emini was clearly on notice of protests that had been going on in the lab because he directed Krah's staff to follow Krah's orders to ensure the "enhanced" testing would be

successful. He also told the staff that they had earned very large bonuses for the work they had completed on the project so far and that he was going to double the bonuses and pay them once the testing was complete.

54. In July 2001, after completing the secret audit, Relator Wlochowski openly accused Krah during a lab meeting of committing fraud in the mumps testing. Relator Krahling then met with Alan Shaw, the Executive Director of Vaccine Research and confronted him about the fraudulent testing. Krahling told Shaw of the falsification of the pre-positive data. He also confronted Shaw about the improper use of the animal antibodies to inflate the post-vaccine neutralization counts. Shaw responded that the FDA permitted the use of the animal antibodies and that should be good enough for Krahling. Shaw refused to discuss anything further about the matter. Instead, Shaw talked about the significant bonuses that Emini had promised to pay the staff in Krah's lab once the testing was complete.

55. Relator Krahling then met with Bob Suter, Krahling's human resources representative at Merck. Krahling told Suter about the falsification of data and Shaw's refusal to get involved. Krahling told Suter that he was going to report the activity to the FDA. Suter told him he would go to jail if he contacted the FDA and offered to set up a private meeting with Emini where Krahling could discuss his concerns.

56. Shortly thereafter, Emini agreed to meet with Krahling. In the early August, 2001 meeting with Emini, Krahling brought actual testing samples and plaque counting sheets to demonstrate to Emini the fraudulent testing that Krah was directing. Emini agreed that Krah had falsified the data. Krahling also protested against the use of the animal antibodies to inflate the seroconversion rate. Emini responded that the animal antibodies were necessary for Merck to

achieve the project's objective. Krahling proposed a scientific solution to lower the pre-positive rate and end the need to falsify data -- stop using the animal antibodies. When Emini declined, Krahling asked him what scientific rationale justified using the animal antibodies. Emini explained that Merck's choice to use the antibodies was a "business decision."

57. To assuage Krahling's concerns, Emini promised to conduct an "internal audit" of the mumps testing. Krahling countered that the FDA should be contacted since only the FDA could perform an audit that was truly independent. Emini ordered Krahling not to call the FDA. Immediately after the meeting, Suter approached Krahling and again threatened that he would be put in jail if he contacted the FDA.

58. The next morning, Krah arrived early to the lab and packed up and destroyed evidence of the ongoing mumps testing. This evidence included garbage bags full of the completed experimental plates, containing the cell sheets with plaques, that would have (and should have) been maintained for review until the testing was complete and final. The destruction of the plates would make it difficult to compare the actual plaque counts in the test with what was documented and changed on the counting sheets, as Krahling had done the day before in Emini's office. Despite the threats he received from Suter and Emini, Krahling called the FDA again and reported this latest activity in Merck's ongoing fraud.

E. The FDA Interview of Krah and Shaw

59. On August 6, 2001, in response to Relator Krahling's repeated calls, an FDA agent came to Merck to question Krah and Shaw. The FDA agent's questions were largely focused on Merck's process for counting plaques in the "enhanced" PRN test. Krah and Shaw

misrepresented the process that Merck was actually conducting and the fact that Merck was falsifying the pre-positive test data.

60. For example, the FDA agent asked whether there was any *ad hoc* revisiting of plaque counts. Krah falsely responded that plaque counts were being rechecked only for verification, controls and to check hypervariability. Krah also misrepresented to the FDA that they did not change the data after it was entered in the excel workbook. When the FDA agent pressed Krah on the criteria for changing original counts on the counting sheets, Krah left the interview without answering the question. In Krah's absence, Shaw informed the FDA agent that a memo would be added to the standard operating procedure to address changes. The FDA agent then asked Shaw why they had not taken care of this before the project started. Shaw offered that Krah and another Merck employee had identified "trends" and "problems" with the original counts without ever explaining what those "trends" or "problems" actually were.

61. The interview proceeded in this manner with Shaw and Krah obfuscating what was happening in the lab and obstructing the FDA's efforts to find out what was really going on with Merck's manipulation of the testing procedure to reach its targeted seroconversion rate.

62. The entire interview with Krah and Shaw was short, probably less than half an hour. The FDA agent did not question Relators Krahling or Wlochowski or other members of Krah's staff in order to corroborate what Krah and Shaw said. As far as Relators witnessed, the FDA agent did not attempt to substantiate Krah's or Shaw's responses by reviewing any of the testing samples or backup data that had escaped destruction. And the FDA agent did not address the actual destruction of evidence that Krah had already facilitated.

63. The FDA issued a one page deficiency report identifying a few relatively minor shortcomings in Merck's testing process. These principally related to flaws in Merck's record-keeping and in its validation/explanation of changes to the test data.

64. The report did not address or censure Merck for any issues relating to Merck's improper use of the animal antibodies or Merck's wide-scale falsification of pre-positive test data. The FDA did not discover this fraudulent activity in the course of the perfunctory visit because of Krah's and Shaw's misrepresentations to the FDA.

F. Merck's Completion and Use of the Fraudulent Test Results

65. In order to comply with the FDA's deficiency report, Merck made minor adjustments to its testing procedure relating to its heretofore *ad hoc* procedure for counting plaques. The new, more formalized procedure explicitly provided for supervisory oversight and review of plaque counts in pre-vaccinated blood samples and where plaques were difficult to read because of the condition of the sample. In other words, under the "new" procedure, Merck continued to falsify the test data to minimize the level of pre-positives and inflate the seroconversion rate.

66. After the FDA visit, Relator Krahling was barred from any further participation in the Protocol 007 mumps vaccine testing project. He was also prohibited from accessing any data related to the project. Shortly thereafter, he was given a poor performance review and barred from continuing to work in Krah's lab on any matter. He was offered a position in a different lab within Merck's vaccine division, but it involved work for which Krahling had no prior experience or interest. In December, 2001 Krahling resigned from the company.

67. Relator Wlochowski continued to work at Merck, though she was transferred out of Krah's lab at the end of September, 2001. She spent an additional year working at Merck in a different lab before she too left Merck.

68. Before Relators Krahling and Wlochowski left Krah's lab, Merck conducted the internal audit Emini had promised Relator Krahling would take place. However, as Krahling had warned against, the audit was anything but independent. Unsurprisingly, therefore, Merck completed its Protocol 007 testing in late summer or early fall 2001 and Merck reported the 95 percent seroconversion it had targeted from the outset. What no one knew outside of Merck -- not the FDA, the CDC or any other governmental agency -- was that this result was the product of Merck's improper use of animal antibodies and the wide-scale falsification of test data to conceal the significantly diminished efficacy of its vaccine.

69. Notably, while Relators Krahling and Wlochowski were immediately removed from Krah's lab for their protests against and efforts to stop the fraudulent testing, those that facilitated the fraud remained. Indeed, Krah, Yagodich and other members of Krah's staff who were instrumental in the fraud continue to work in vaccine development at Merck today and are still working together in Krah's lab.

MERCK'S ONGOING FRAUDULENT REPRESENTATION OF A 95 PERCENT EFFICACY RATE

70. Since at least the beginning of the Protocol 007 testing and continuing through the present, Merck has falsely represented to the government and the public that its mumps vaccine has at least a 95 percent efficacy rate. It has done so even though Merck is well aware, and has taken active steps to keep secret, that the efficacy rate is far lower.

A. Merck's False Representations Through Package Inserts

71. Merck principally has made these false representations in the package insert or labeling that accompanies each dose of Merck's vaccine. This is the product material that the law requires which, among other things, informs the government, health care providers and the public of the composition of the vaccine and its overall efficacy at immunizing the recipient from contracting mumps.

72. Merck's mumps vaccine insert has changed over the years, but at least one thing has remained constant -- Merck's reporting of at least a 95 percent efficacy rate. The current package insert for MMRII provides that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons." Merck neither identifies the study performed or the date it was performed that supposedly support this representation. The current insert further provides that: "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." As support for this representation, Merck cites the more than forty-year old studies it conducted to obtain the original governmental approval for a mumps vaccine in 1967. Merck's MMRII package insert has contained this language and "support" since at least 1999.

73. Merck's product insert is a clear misrepresentation of the efficacy rate of its mumps vaccine. It cites outdated or unidentified studies that are not reflective of what Merck knows now about the vaccine's current effectiveness as confirmed by Merck's efforts to manipulate the methodology and ultimately falsify the data to report at least 95 percent seroconversion. In short, as Merck well knows, the efficacy rate of its mumps vaccine is not

anywhere near 95 percent. Yet, Merck continues to falsely represent a 95 percent efficacy rate to ensure its continued lock on the sale of the vaccine in the U.S.

B. Merck's False Representations Through Expanded Distribution of the Vaccine

74. Merck's misrepresentations relating to its mumps vaccine have not been made just to the U.S. government for MMRII. Merck has also obtained approval to sell MMRII in Europe and to sell ProQuad in the U.S. and Europe. Merck obtained these approvals by again misrepresenting to the FDA (in the U.S.) and the EMA (in Europe) the efficacy rate of its mumps vaccine.

75. In 2004 Merck submitted an application to the FDA for approval of ProQuad. Merck certified the contents of its application were true. In 2005, after reviewing Merck's application, the FDA approved ProQuad. According to the FDA's clinical review of the studies Merck submitted in support of ProQuad, "[c]linical efficacy of … mumps … vaccine strain w[as] shown previously … using [the] monovalent. [T]he vaccine response rates were 95.8 to 98.8% for mumps." Merck knew from its Protocol 007 testing that this falsely represented the efficacy of its mumps vaccine. Now that it is licensed, Merck's package insert continues to misrepresent the efficacy of its mumps vaccine, stating: "Clinical studies with a single dose of ProQuad have shown that vaccination elicited rates of antibody responses against measles, mumps, and rubella that were similar to those observed after vaccination with a single dose of M-M-R II" and "[a]ntibody was detected in 96.7% for mumps."

76. In 2006, Merck obtained a license from the EMA to sell the MMRII analogue (called MMRVaxpro) through the joint venture Sanofi Pasteur MSD. Merck used the falsified results of the "enhanced" PRN test to obtain this approval. The EMA actually cited Protocol 007

as a "pivotal clinical study" in support of its decision to grant the approval. Since then, Merck has been manufacturing MMRVaxpro at its West Point facility for Sanofi Pasteur MSD to sell in Europe.

77. Around the same time, Merck also obtained a license from the EMA for Sanofi Pasteur MSD to sell Merck's ProQuad in Europe. As with MMRVaxpro, Merck's joint venture submitted the falsified results of Protocol 007 to the EMA as supportive clinical information in its vaccine application. Relying on this information, the EMA found "no major concern" about the efficacy of the mumps component of the vaccine.

78. Thus, by 2006, Merck had the exclusive licenses to sell MMRII and ProQuad in the U.S., as well as licenses to sell MMRVaxpro and ProQuad in Europe. Throughout this time, Merck falsely represented an efficacy rate of 95 percent or higher and engaged in scientifically deficient testing and outright fraud to assure this was the efficacy rate consistently associated with its mumps vaccine.

C. Merck's False Representations Through Its Application for a Labeling Change on Potency of MMRII

79. In 2007, Merck changed its MMRII labeling to reflect a decrease in the potency of the mumps component of the vaccine. Potency measures how much of the attenuated virus is included in each dose of the vaccine. The labeling change -- approved by the FDA -- allowed Merck to represent a lower minimum potency, from 20,000 to 12,500 $TCID_{50}$ (or tissue culture infective dose, which is the scientific measure of vaccine potency). This represented a 37.5 percent reduction in how much of the attenuated virus could go into each dose of the vaccine.

80. At no time during Merck's efforts to secure approval to change its MMRII labeling did Merck disclose to the FDA what Merck knew about the diminished efficacy of the vaccine. Nor did Merck take any steps to address the efficacy information that was falsely represented in the labeling. That portion of the labeling remained unchanged.

81. Merck was thus representing throughout the approval process that it could actually *reduce* how much attenuated virus Merck put into each vaccine shot and still maintain its represented 95 percent efficacy even though Merck knew that at the *higher* potency the vaccine was nowhere near this efficacy. Clearly, if the FDA had known the truth about the vaccine's efficacy it would not have approved the labeling change to reduce the minimum potency.

D. Merck's False Representations Through Recent Mumps Outbreaks

82. With Merck's significantly degraded vaccine as the only protection against the mumps in this country, there has remained a significant risk of a resurgence of mumps outbreaks. That is exactly what Krah -- who was well aware of the mumps vaccine's failings -- predicted would occur. In a conversation he had with Relator Krahling in the midst of the "enhanced" PRN testing, Krah acknowledged that the efficacy of Merck's vaccine had declined over time, explaining that the constant passaging of virus to make more vaccine for distribution had degraded the product. Krah predicted that because of this, mumps outbreaks would continue. And that is exactly what has happened.

1. <u>The 2006 Mumps Outbreak</u>

83. In 2006, more than 6,500 cases of mumps were reported in the Mid-West in a highly vaccinated population. This was the largest mumps outbreak in almost twenty years and a

significant spike from the annual average of 265 cases that had been reported for the years leading up to the 2006 outbreak.

84. The CDC, FDA and Merck publicly worked together to determine the cause of this 2006 outbreak. Of course, only Merck knew that outbreaks would occur because its vaccine had degraded over time and was weaker than what Merck represented. Nonetheless, Merck continued to represent its inflated efficacy rate and the government continued to believe that there was no problem with the vaccine. During the investigation of the outbreak, the CDC's then Director, Julie Gerberding, reaffirmed the CDC's view that nothing was wrong with the mumps vaccine, a belief fed by Merck's continued misrepresentations: "*We have absolutely no information to suggest that there is any problem with the vaccine.*" Director Gerberding and the CDC emphasized that "[t]he best protection against the mumps is the vaccine."

85. Even though Krah, the Merck investigator who ran Protocol 007, expected outbreaks to increase because of the degraded product, scientists at the CDC and elsewhere continued researching to understand the origins of such a large outbreak within a highly vaccinated population. One of the leading studies was led by Dr. Gustavo Dayan, then a doctor at the CDC, and published in 2008 in the *New England Journal of Medicine*. After considering possible causes for the outbreak, Dr. Dayan recommended that "[f]uture studies will help evaluate national vaccine policy, including whether the administration of a second dose of MMR vaccine at a later age or the administration of a third dose would provide a higher or a more durable immunity." Gustavo H. Dayan, "Recent Resurgence of the Mumps in the United States," *New England Journal of Medicine*, 358;15 (Apr. 10, 2008) 1580.

86. Dr. Dayan's study ultimately concluded that "[a] more effective mumps vaccine or changes in vaccine policy *may* be needed to avert outbreaks and achieve elimination of mumps." *Id.* (emphasis added). Of course, if Dr. Dayan had the benefit of what Merck knew but willfully withheld from the government and the public, his findings would have been significantly less equivocal on what needed to be done to stop the reemergence of mumps outbreaks.

87. At the same time Dr. Dayan published his study questioning whether it may be time for a new vaccine, Merck publicly proclaimed that its mumps vaccine had not been changed since its introduction in 1967 and that Merck had no plans to change it. So, while Dr. Dayan questioned whether it "may" be time for a new vaccine, Merck attempted to reassure the public that there was no need for any such change. The vaccine worked just fine.

88. In another study on the 2006 outbreak, several scientists questioned Merck's use of the Jeryl Lynn strain, instead of the wild-type virus, in Merck's PRN testing. They noted that with this kind of testing, vaccine efficacy can be significantly overstated because "good results can be obtained that do not reflect the actual ability of the vaccine to provide protection from disease. A vaccine failure is investigated properly only if, in addition to avidity testing, the ability of antibodies to neutralize wild mumps virus has been checked." Heikki Peltola, *et. al.*, "Mumps Outbreaks in Canada and the United States: Time for New Thinking on Mumps Vaccine," *Clinical Infectious Diseases*, 2007:45 (15 Aug. 2007) 459, 463.

89. What is perhaps most notable about this study is that it scientifically questioned Merck's stated efficacy based solely on Merck's use of the vaccine strain instead of the wild type virus to test efficacy. The critique did not (and could not) even account for Merck's concealed

efforts to further inflate its efficacy results with the improper use of animal antibodies and the falsification of test data.

90. Currently, Emory University is conducting a clinical trial of its university students in yet another attempt to explain the cause for the 2006 mumps outbreak among college-age students who had received both doses of the vaccine. However, Merck is listed as a collaborator on that study, thus continuing to position itself to perpetuate its fraudulent efficacy findings.

91. Merck's ongoing misrepresentations and omissions with respect to the effectiveness of its vaccine continue to conceal the role its degraded product played in the 2006 outbreak.

2. The 2009 Mumps Outbreak

92. In his 2008 study, Dr. Dayan also predicted another mumps outbreak would follow three years after the 2006 outbreak. This followed from the three-year cycles in which outbreaks occurred before children were widely vaccinated for mumps. "[I]n the pre-vaccine era, mumps activity followed 3 year cycles, so the current low activity rate [at the time of his 2008 study] may be transient while another critical mass of susceptible persons accrues." Dayan, *New England Journal of Medicine*, 358;15 at 1587-88.

93. In August 2009, another mumps outbreak began just as Dr. Dayan predicted. As with the 2006 outbreak, the 2009 outbreak occurred despite high vaccination coverage among the U.S. children's population. In total, roughly 5,000 cases were confirmed by the CDC during the 2009 outbreak. This outbreak reaffirmed Krah's prediction that mumps outbreaks would reemerge and increase over time.

94. Faced with a mumps outbreak in 2006, and without complete information as to what might have caused it, the CDC acknowledged that it would consider the possibility of recommending a third dose of mumps vaccine. According to the Deputy Director of the CDC's Viral Diseases division in 2008, "If there's another outbreak, we would evaluate the potential benefit of a third dose to control the outbreak."

95. Because of the 2006 and 2009 outbreaks, the CDC has also pushed back its target date for eradicating mumps from its original 2010 goal to no earlier than 2020. But no amount of extra time or dosages will be enough to eliminate the disease when the vaccine does not work as represented in the labeling. It will merely allow Merck to continue to misrepresent the vaccine's efficacy and thereby maintain its exclusive hold on the mumps market with an inadequate vaccine.

96. To date, the government has not acted on Dr. Dayan's conclusion that it "may" be time for a new mumps vaccine. Instead, it continues to build its strategy around the existing vaccine. Nor is Dr. Dayan likely to pursue his own conclusion. He left the CDC to take a position in the Clinical Department of Sanofi Pasteur, the vaccine division of the Sanofi Aventis Group, Merck's partner in manufacturing and selling MMRVaxpro and ProQuad in Europe. Dr. Gerberding has also left the CDC. In January 2010, she became the president of Merck's Vaccine Division, a position she holds currently.

E. Merck's False Representations Through the Immunization Action Coalition

97. The Immunization Action Coalition (IAC) is a non-profit organization which describes itself as the "nation's premier source of child, teen, and adult immunization information for health professionals and their patients." It provides educational materials and "facilitates

communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, health care organizations, and government health agencies."

98. The CDC works closely with the IAC. Indeed, "[a]lmost all of IAC's educational materials are reviewed for technical accuracy by immunization experts at the CDC." The CDC also provides the IAC with financial support for the purpose of educating health care professionals about U.S. vaccine recommendations. Several CDC physicians currently serve on IAC's Advisory Board. So does the current Director of the National Vaccine Program Office at the Department of Health and Human Services.

99. Merck also provides funding to the IAC.

100. The IAC asserts that Merck's mumps vaccine has an efficacy rate of 97 percent. This comes from the following mumps vaccine "Question and Answer" information sheet posted on the IAC's website: "**How effective is this vaccine**? The first dose of MMR vaccine produces good immunity to … mumps (97%)."

101. Merck has done nothing to correct this widely disseminated misinformation, sanctioned and supported by the CDC, about the efficacy of Merck's mumps vaccine. If anything, through its funding and support of the IAC, Merck has once again positioned itself to facilitate the spread of this false efficacy information. Clearly, if the CDC were aware of the true efficacy of Merck's mumps vaccine and the effort Merck has undertaken to conceal it, the CDC would take steps to correct the IAC's information on the vaccine.

IN FRAUDULENTLY REPRESENTING AND OTHERWISE CONCEALING THE DIMINISHED EFFICACY OF ITS MUMPS VACCINE, MERCK HAS VIOLATED ITS MULTIPLE DUTIES UNDER THE U.S. VACCINE REGULATORY REGIME

102. There are three principal components to the government regulation and purchase of vaccines in this country. The CDC is responsible for the government's purchase of vaccines and for educating the public on, among other things, the safety and efficacy of vaccines and the importance of immunization. The FDA is responsible for overseeing the licensing and approval of vaccines, their manufacture and distribution, and how they are represented to health care professionals and the public through vaccine labeling. The National Vaccine Program, of the Department of Health and Human Services, is responsible for generally overseeing the U.S. vaccine program, including coordinating with the various agencies involved in the program and manufacturers like Merck, and ensuring that vaccines are safe and effective and in sufficient supply.

103. A critical underpinning of this overlapping vaccine regulatory framework is that each agency involved has accurate and up-to-date information on the safety and efficacy of the various vaccines licensed for use in this country. This information is particularly important for the CDC which purchases the vaccines pursuant to a contract with Merck. Not only does it decide which vaccines the government will purchase. It also creates the schedule of recommended vaccinations that determines those vaccines that children in public school are required to take. Furthermore, as codified in the National Childhood Vaccine Injury Act, the CDC has the duty to warn the public about the safety and efficacy of the vaccines. Notably, this is a duty that Merck was instrumental in establishing.

104. Merck thus has ongoing and independent duties to disclose to these agencies all material information relating to the safety and efficacy of its mumps vaccine. However, in misrepresenting a falsely inflated efficacy rate for its mumps vaccine and concealing what Merck knew about the significantly diminished efficacy of the vaccine, Merck has breached these multiple duties.

A. Merck's Duties to the CDC

1. Merck's Duty to Disclose Diminished Efficacy

105. Merck has both a contractual and statutory duty to provide the CDC with accurate information regarding the safety and efficacy of its mumps vaccine. This duty is triggered by Merck's contractual and statutory delegation to the CDC of Merck's duty to warn the public about the vaccine's safety and efficacy. Without this delegation, Merck would be responsible – as any drug manufacturer would -- for providing adequate information to consumers relating to the risks and benefits of the vaccine.

106. Merck and the CDC first agreed to this delegation back in the 1970's, at Merck's suggestion. It provided a way to assure that the CDC could purchase Merck's vaccines without Merck being subjected to personal injury claims for failing to warn individual vaccinees or their parents about the safety and efficacy of vaccines administered through government vaccination programs. As a result of the parties' negotiation, the CDC assumed the duty to warn with respect to all Merck vaccines it purchases. In exchange Merck agreed to provide the CDC with all of the information the CDC needs to adequately carry out the duty to warn.

107. This means that Merck has an ongoing duty to provide the CDC with accurate information on the efficacy of its mumps vaccine, including apprising the CDC of any problems

Merck discovers, or in the exercise of reasonable care should have discovered, associated with the vaccine's stated efficacy. In the absence of any direct communications by Merck to the CDC relating to the vaccine's efficacy, the CDC principally relies on Merck's vaccine package insert for this information.

108. Merck benefits greatly from this arrangement as it protects Merck from liability for personal injury claims based on any failure to provide consumers with adequate warnings about the vaccine. All of the Merck-CDC purchase contracts (dating back from the late 1970s) contain language, originally drafted by Merck's counsel, providing that the CDC agrees to "take all appropriate steps to provide meaningful warnings [to consumers] relating to the risks and benefits of vaccination."

109. This delegation is now codified under the National Childhood Vaccine Injury Act which, among other things, requires the CDC to develop and disseminate vaccine information materials which provide: "(1) a concise description of the benefits of the vaccine, ... and (4) such other relevant information as may be determined by the Secretary [of Health and Human Services]." 42 USC § 300aa-26(c). Merck-CDC purchase contracts still contain the delegation of the duty to warn, but now also cite to this provision as the relevant authority. The CDC also cites to this provision in the Vaccine Information Statements it publishes apprising vaccinees and their parents or guardians of the purpose, risks and benefits of a particular vaccine.

110. The Act further provides a notable (and logical) exception to the statutory release from liability of a vaccine manufacturer for a failure to warn. It does not apply if the manufacturer engages in "intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval." Indeed, under such circumstances, the

manufacturer can be held liable for punitive damages for any failure to warn. 42 USC § 300aa-23(d)(2)(A) and (B).

111. As the Third Circuit has held, Merck's duty to provide accurate and up-to-date safety and efficacy information to the CDC is unequivocal and ongoing: "The manufacturer's responsibility is continuous, and it must therefore apprise the CDC of any risks it later discovers, or in the exercise of reasonable care, should have discovered." *See Mazur v. Merck*, 964 F2d 1348, 1365-66 (3rd Cir. 1992).

2. Merck's Additional Contractual Duties to the CDC

112. The Merck-CDC purchase contracts also obligate Merck to comply with various FDA regulations regarding the manufacture and sale of its vaccines. This includes the requirements that Merck only sell vaccines to the CDC that are licensed by the FDA and manufactured in conformance with the FDA's current Good Manufacturing Procedures ("cGMP"). As discussed below, a vaccine that is not manufactured in conformance with the specifications upon which the government's approval is based -- such as diminished efficacy -- fails to comply with cGMP and thus violates the CDC purchase contract. As also described below, a vaccine that is mislabeled, misbranded or adulterated (such as with a package insert that represents an inflated efficacy rate), or falsely certified as compliant with the conditions of purchase, likewise violates the CDC purchase contract.

B. Merck's Duties to the FDA

113. Merck has ongoing duties to the FDA pursuant to the Public Health Service Act, the Food Drug and Cosmetics Act and FDA regulations that control the licensing, labeling and manufacture of vaccines. 21 USC § 301 *et seq.*; 42 USC § 262 *et seq.*

1. Merck's Duty to Disclose Diminished Efficacy

114. Vaccine manufacturers have an ongoing duty to report problems with efficacy. 21 CFR § 600.12(b).

115. Vaccine manufacturers also have an ongoing duty to manufacture vaccines in conformance with cGMP. 21 CFR § 210.2. In order to ensure compliance with cGMP, vaccine manufacturers are required to test for safety, purity, and potency every lot of the vaccine to be sold. 21 CFR § 610. Per the specifications approved by the FDA for Merck's mumps vaccine, this means that the amount of attenuated virus Merck puts in its vaccine result in a minimum 95 percent efficacy. *See* 21 CFR § 600.3(s) (Potency is defined as the "[a]bility ….to effect a given result"). If a manufacturer learns of a deviation from the specifications (such as diminished efficacy), it has a duty to disclose that information to the FDA, fully investigate it and correct it. 21 CFR § 600.14; 21 USC § 331(e) and 21 CFR § 211.192. A vaccine that does not comply with these standards is considered an adulterated product that cannot legally be sold. 21 USC § 331(a).

116. Vaccine manufacturers also have an ongoing duty to report to the FDA all adverse experience events (such as diminished efficacy). *See*, 21 CFR § 600.80. Failure to report an adverse event may result in revocation of the license for the product. 21 CFR § 600.80(j). The law also imposes additional reporting requirements for vaccines, such as Merck's mumps vaccine, used in the pediatric population. It requires vaccine manufacturers to submit annual reports of any post-marketing pediatric studies to, among other things, inform the FDA of whether new studies in the pediatric population have been initiated. These reports must include

an analysis of available safety and efficacy data in the pediatric population, and an assessment of data needed to ensure appropriate labeling for the pediatric population. 21 CFR § 601.28.

2. Merck's Duty to Ensure that Its Mumps Vaccine Package Insert Is Neither False Nor Misleading

117. Vaccine manufacturers are at all times responsible for the content of their labeling, including their package insert. They are charged both with crafting adequate and accurate labeling and with ensuring that the information remains adequate and accurate. This includes an ongoing duty to self-monitor and update their labeling -- including all associated package inserts and information sheets -- when new information becomes available that causes the labeling to become inaccurate, false or misleading. 21 CFR § 601.12 (f)(2) and 21 CFR §201.56-57. A vaccine is deemed to be misbranded and mislabeled, and cannot be sold, if its labeling is "false or misleading in any particular." 21 USC §§ 352(a) and 331(a).

C. Merck's Duties to the National Vaccine Program

118. Merck also has duties under the National Childhood Vaccine Injury Act which created the National Vaccine Program and the Vaccine Injury Compensation Program. The two programs together were intended to create a simple, easy to administer system for vaccine injury compensation (which Merck wanted) and a more stable, competitive market for childhood vaccines which would lead to vaccine improvements (which the government wanted). The manufacturers were deemed stakeholders and enlisted to collaborate and cooperate with the government to improve the country's vaccination program. In exchange, under the Injury Compensation Program, Merck and other manufacturers obtained protection from liability for personal injury claims.

119. The Act also created a new system for manufacturers to report all "adverse events" related to vaccines reinforcing the reporting requirements otherwise triggered by the Public Health Service Act and the Food Drug and Cosmetics Act, described above. These adverse event reports are made on the Vaccine Adverse Event Reporting System and are supposed to encompass any problems associated with a vaccine including those associated with safety and efficacy. 42 USC § 300aa-25(b).

D. Merck's Duty to Be Truthful and Forthcoming In Its Dealings With the Government

120. Merck has a duty to be forthcoming and honest with federal officials in all of its dealings with the government. Specifically, under 18 USC § 1001, Merck is prohibited from knowingly and willfully: (1) falsifying, concealing, or covering up a material fact by any trick, scheme, or device; (2) making any materially false, fictitious, or fraudulent statement or representations; or (3) making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in any matter relating to the government.

E. Merck's Breach of These Multiple Duties to the Government

121. Merck breached all of the above duties by falsely representing that the efficacy rate of its mumps vaccine is 95 percent or higher and by taking affirmative steps to conceal the vaccine's diminished efficacy.

122. These duties were triggered as soon as Merck learned that the efficacy of its now forty-five year old mumps vaccine had diminished. Merck learned this no later than 1999 as evidenced by the admission by the head of the Merck team running the Protocol 007 testing,

Krah. He even correctly predicted that the diminished efficacy of the vaccine would lead to the reemergence of mumps outbreaks. But rather than disclose this to the CDC, FDA or the appropriate individuals running the National Vaccine Program, as Merck was obligated to do, Merck instead embarked on a campaign of concealment and outright fraud.

123. First, Merck devised a scientifically flawed PRN test which attempted to measure the efficacy of its mumps vaccine based on how the vaccine performed against the less virulent vaccine strain of the virus rather than the wild-type strain that exists in the real world. Even using this scientifically dubious methodology, Merck saw that the seroconversion rate was significantly lower than the 95 percent efficacy rate that Merck was representing on its labeling and otherwise. Merck abandoned this methodology and its unfavorable results and kept them hidden rather than disclose them to the government.

124. Second, Merck devised an even more scientifically flawed PRN test when it "enhanced" its 1999 test with animal antibodies. The new methodology was not selected to provide a more accurate measure of the vaccine's efficacy. To the contrary, the methodology was concocted to measure a high seroconversion rate rather than an accurate one. To ensure that Merck's manipulation remained disguised, it falsified the test data to guarantee the pre-negative to post-positive change needed to achieve seroconversion. Having reached the desired, albeit falsified, efficacy threshold, Merck submitted these fraudulent results to the FDA (and the EMA in Europe), again breaching its multiple duties of open and honest disclosure to the government.

125. Third, Merck took steps to cover up the tracks of its fraudulent testing by destroying evidence of the falsification and lying to the FDA investigator that questioned Merck about the ongoing testing. Merck also attempted to buy the silence and cooperation of the staff

involved in the testing by offering them financial incentives to follow the direction of the Merck personnel overseeing the fraudulent testing process. Merck also threatened Relator Krahling on numerous occasions with jail if he reported the fraud to the FDA.

126. Fourth, in 2004 Merck submitted the application for approval for ProQuad, certifying the contents of the application as true even though Merck knew the statements about the effectiveness of the mumps vaccine were, in fact, false. At no time during this application process did Merck disclose to the FDA the problems of which it was aware (or should have been aware) relating to the significantly diminished efficacy of its mumps vaccine. Accordingly, in 2005, the FDA approved Merck's application for ProQuad.

127. Fifth, Merck sought and secured FDA approval to change its MMRII labeling to reflect an almost 40 percent reduction in the minimum potency of the mumps vaccine component. It did this while leaving its false representations of efficacy unchanged. And it did this fully appreciating that if the current, higher potency vaccine had an efficacy rate far lower than the falsely represented 95 percent, there was no way the vaccine would achieve this efficacy with significantly less attenuated virus in each shot. Nevertheless, at no time during the course of obtaining the FDA's approval for the labeling change did Merck disclose to the FDA the problems of which it was aware (or should have been aware) relating to the significantly diminished efficacy of its vaccine. Nor did Merck disclose its knowledge that these problems would be greatly exacerbated if the potency in the dose was reduced.

128. Sixth, Merck continued to conceal what it knew (or should have known) about the diminished efficacy of its mumps vaccine even after the 2006 and 2009 mumps outbreaks. It did

so even after the CDC -- with which Merck was supposedly working to determine the cause of the outbreaks -- publicly stated that there was nothing wrong with the vaccine.

129. Seventh, Merck has continued to conceal what it knows (or should know) about the diminished efficacy of its mumps vaccine even though the Immunization Action Coalition -- which Merck funds, and which the CDC also funds, supports and substantively contributes to -- prominently promotes an efficacy rate of 97 percent.

130. And eighth, despite what Merck knows (or should know) about the diminished efficacy of its mumps vaccine, Merck has fraudulently represented on its labeling a significantly inflated efficacy rate. Not only does this violate each of the multiple duties described above and make Merck's mumps vaccine a mislabeled, misbranded and adulterated product. This continuous misrepresentation falsely certifies to the government compliance with the terms of the contract pursuant to which the government buys Merck's vaccine.

131. Merck's broad-based scheme to falsely represent and conceal the diminished efficacy of its mumps vaccine violated the multiple duties it owes the government to report, investigate and attempt to correct any problems associated with the safety and efficacy of its vaccine, including its duty: (i) to the CDC, to provide accurate and up-to-date efficacy information and comply with cGMP requirements and not to sell mislabeled, misbranded or adulterated products; (ii) to the FDA, to provide accurate and up-to-date efficacy information, comply with cGMP requirements, fully and properly investigate, test, and correct any suspected problems with efficacy, and ensure the efficacy information reported on Merck's labeling is neither false nor misleading; (iii) under the National Vaccine Program, to report all "adverse

events" related to its vaccines including problems associated with efficacy; and (iv) to the government generally, to be forthcoming and honest in all of Merck's dealings.

IN FRAUDULENTLY REPRESENTING AND OTHERWISE CONCEALING THE DIMINISHED EFFICACY OF ITS MUMPS VACCINE, MERCK HAS ILLEGALLY MONOPOLIZED THE MUMPS VACCINE MARKET

132. As the only company licensed by the government to sell mumps vaccine, Merck has had a monopoly in the U.S. market for mumps vaccine since it obtained its original license in 1967. However, Merck has maintained this monopoly not through its business acumen or its manufacture and sale of the best quality product. Instead, Merck has willfully and illegally maintained its monopoly through its ongoing misrepresentations of the efficacy of its mumps vaccine, and its violations of the multiple duties of disclosure it owes the government. Through this misconduct, Merck has been able to maintain a falsely inflated efficacy rate for its mumps vaccine and exclude competing manufacturers from entering the market.

A. The U.S. Market for Mumps Vaccine

133. The U.S. manufacture and sale of mumps vaccine (including Mumpsvax, MMRII and ProQuad) is a relevant antitrust market in this case. For those seeking immunization for mumps, a mumps vaccine is the only product available to achieve that result. So regardless of the price Merck charges for its mumps vaccine, the extent or frequency of any price increases for the vaccine, or whether Merck incorporates the vaccine into multi-disease vaccines, as it does with MMRII and ProQuad, there are no alternative products to which the government, health care professionals or consumers can turn to obtain this immunization.

134. The U.S. market for mumps vaccine is further defined by the CDC's nationwide schedule of recommended childhood vaccinations, including a vaccination against mumps, and

the requirement around the country that all public school students be vaccinated against mumps (among other childhood diseases). If a child is to attend public school -- not to mention any private school, university, summer camp or other educational or recreational institution in this country -- he or she must take a mumps vaccine. There is no choice (but for rare exceptions). There is no alternative. No other products can substitute for this required vaccination.

B. Merck's Monopolization of the Market for Mumps Vaccine

135. Since it originally obtained government approval for the mumps vaccine in 1967, Merck has had a natural monopoly through its de facto exclusive license to sell the vaccine in this country. This has extended to multi-disease vaccines such as MMR, MMRII and ProQuad. But Merck has been able to maintain its monopoly not through providing the safest, most effective and most cost effective mumps vaccines in the market. Rather, Merck has maintained its monopoly by representing a falsely inflated efficacy rate of 95 percent or higher.

136. There are significant barriers to entry inherent in the manufacture and sale of a new vaccine. The research, development, testing and government approval process is very expensive, time-consuming and risky. Several years and millions of dollars might be spent on developing a vaccine only to find it fail in the final stages of testing, or to have the government refuse to approve it or significantly limit its application or distribution. Vaccine manufacturers will therefore invest in developing a new vaccine only where they see both a need for the vaccine and an opportunity to make a large enough return on the significant capital investment and risk involved.

137. In the case of the U.S. market for mumps vaccine, this inherent barrier to entry is substantially compounded by the falsely inflated efficacy rate of Merck's vaccine. As with the

market for any product, a potential competitor's decision to enter a market hinges on whether its product can compete with those products already being sold in the market. If an existing vaccine is represented as safe and at least 95 percent effective, as Merck has falsely represented its vaccine to be, it would be economically irrational for a potential competitor to bring a new mumps vaccine to the market unless it thought it could compete with the safety and efficacy of the existing vaccine. No one would purchase it otherwise -- not the government, nor health care providers, nor consumers.

138. This is especially true for the federal government since its goal in purchasing vaccines is to allocate its resources to reduce and eliminate disease to the fullest extent possible. Using an inferior vaccine would significantly undermine the overarching purpose of the government funded immunization programs. It would specifically interfere with the government's goal, albeit unrealistic in light of Merck's defective vaccine, of eradicating mumps by the end of the decade.

C. Merck Has Maintained Its Monopoly By Foreclosing Competition

139. Through its false representations of the mumps vaccine's efficacy rate, its efforts to conceal the significantly lower efficacy rate that the Protocol 007 testing confirmed, and its repeated violations of the multiple duties of disclosure it owes the government, Merck has foreclosed potential competitors from entering the market with a new mumps vaccine. No manufacturer is going to sink the time, energy and resources into developing the vaccine for sale in the U.S. with the artificially high bar Merck has devised.

140. Entering the market would be particularly risky in the case of the mumps vaccine given the four-decade lock Merck has had on the market.

141. But for Merck's fraud and other misconduct, one or more competing manufacturers would have entered this lucrative market -- with its guaranteed sales of almost 8 million doses a year -- with a competing mumps vaccine. For example, GlaxoSmithKline, a manufacturer of numerous FDA approved vaccines, has an MMR vaccine, Priorix, that is widely sold in Europe, Canada, Australia and other markets. Priorix is not licensed or sold in the U.S.

142. By continuing to misrepresent an artificially high efficacy rate, and engaging in all the misconduct to conceal the diminished efficacy of its vaccine, Merck has foreclosed GlaxoSmithKline and any other manufacturer from entering the U.S. market for mumps vaccine. So long as Merck continues to engage in this misconduct, these manufacturers will continue to be excluded from the U.S. market and Merck will retain its unchallenged monopoly with a vaccine that does not provide adequate immunization.

D. Merck's Harm to Competition and the Government

143. Merck's misconduct has harmed competition by foreclosing other manufacturers from entering the U.S. market for mumps vaccine. Without such competition, Merck has been able to maintain its monopoly in this market even though it is manufacturing and selling a sub-par vaccine. In the absence of this foreclosure, other manufacturers would have entered the market with a higher quality and/or cheaper vaccine. This competition, or the threat of such competition, would have forced Merck to respond by either selling its existing vaccine at a lower price or developing a better vaccine.

144. Merck's misconduct has also harmed the government. It has caused the government to pay Merck hundreds of millions of dollars for a product that is not what Merck represents it to be and not what the government needs it to be. It has also deprived the

government of a competitive market for mumps vaccine which would promote the development of new and better vaccines to improve the health of all Americans. And perhaps most importantly, it has significantly undermined the government's efforts to protect the public against a resurgence of mumps. Outbreaks of the disease have increased and threaten to continue and grow larger. And the original target date for eradication of the disease has long since passed.

THE UNITED STATES' PAYMENT OF HUNDREDS OF MILLIONS OF DOLLARS FOR A VACCINE THAT DOES NOT PROVIDE ADEQUATE IMMUNIZATION

145. Over the past decade, Merck's fraudulent scheme to misrepresent the efficacy of its mumps vaccine has cost the U.S. hundreds of millions of dollars through the government's annual purchases of the vaccine under the National Vaccine Program. Had Merck complied with the U.S. antitrust laws and with its multiple duties of disclosure and reported the diminished efficacy of its vaccine -- rather than engage in fraud and concealment -- it would have affected (or certainly had the potential to affect) the government's decision to purchase the vaccine. The government would have had the opportunity to consider numerous options. For MMRII this would include not purchasing the vaccine from Merck, paying less, requiring a labeling change, requiring additional testing, or prioritizing development and approval of a new vaccine (per the mandate of the National Vaccine Program). For ProQuad this would include not licensing the vaccine at all.

146. But Merck did not comply with these duties of disclosure or with the antitrust laws. Instead, it took pains to maintain its fraudulently inflated efficacy rate and its monopoly grip on the market so it could foist on the government a vaccine without sufficient immunizing effect. In other words, over the past decade, through its scheme of fraud and concealment,

Merck has sold the government a vaccine that (i) is mislabeled, misbranded, adulterated and falsely certified; and (ii) does not comply with the FDA's labeling, reporting and testing requirements; with the CDC's reporting requirements; with the cGMP standards required by the CDC contract and the FDA; and with the requirements of the National Vaccine Program to report any vaccine failure.

147. The CDC plays the critical role of making the government's vaccine purchasing decisions. It is responsible for entering into the contracts with the manufacturers, deciding which vaccines to purchase, providing information on safety and efficacy to health care providers and the public, and promoting the benefits of widespread immunization. The CDC purchases vaccines in batches of varying size throughout the year for administration to the public. As negotiated, Merck ships its vaccines to the CDC's designated repositories. Merck thereafter submits a claim for payment which the CDC subsequently pays.

148. The CDC annually purchases from Merck anywhere from roughly $60 million to $76 million of its MMRII vaccine. This comes from the following approximate calculation:

4 million (annual number of U.S. births)
X
.95 (childhood vaccination rate)
X
2 (number of doses per vaccinated child)
X
.52 (rate of vaccine spending attributed to CDC)
X
15 to 19.33 (dollar price range of MMRII dose from 2000 to present)

The mumps component of the MMRII vaccine represents about 40 percent of the vaccine's total cost.

149. Since 2000, the CDC has thus paid Merck more than $700 million for its MMRII vaccine to be administered to children. These amounts likely underestimate the CDC's total purchases because they do not account for purchases of ProQuad, which is significantly more expensive than MMRII, Mumpsvax, or purchases of adult doses of Mumpsvax, MMRII and ProQuad, which Merck also sells to the CDC. Over this period, the U.S. has therefore paid more than three-quarters of a billion dollars for a mislabeled, misbranded, adulterated and falsely certified vaccine that does not provide adequate immunization.

CLAIM FOR RELIEF
(Merck's Violation of the False Claims Act)

150. Relators reallege and incorporate by reference all of the allegations set forth herein.

151. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

152. As set forth above, in violation of 31 U.S.C. § 3729(a)(1), Merck knowingly presented, or caused to be presented, to the United States government, false or fraudulent claims for payment or approval when it billed the government for its purchases of a mumps vaccine that, among other things, (i) was significantly less effective than Merck represented it to be, (ii) did not provide the product the government contracted to purchase, (iii) was mislabeled, misbranded, adulterated and falsely certified and (iv) was exclusively supplied to the government by Merck because of Merck's illegal monopolization of the mumps market.

153. In addition, at least for conduct occurring on or after May 20, 2009, Merck violated 31 U.S.C. § 3729(a)(1)(A) (formally 31 U.S.C. § 3729(a)(1) as amended by the Fraud

Enforcement and Recovery Act of 2009) by knowingly presenting or causing to be presented false or fraudulent claims for payment or approval when Merck billed the government for its purchases of a mumps vaccine that, among other things, (i) was significantly less effective than Merck represented it to be, (ii) did not provide the product the government contracted to purchase, (iii) was mislabeled, misbranded, adulterated and falsely certified and (iv) was exclusively supplied to the government by Merck because of Merck's illegal monopolization of the mumps market.

154. As set forth above, in violation of 31 U.S.C. § 3729(a)(2), Merck also knowingly made, used, or caused to be made or used, false records or statements to obtain payment or approval by the government of Merck's false or fraudulent claims for purchases of its mumps vaccine when Merck, among others things: (i) failed to disclose that its mumps vaccine was not as effective as Merck represented, (ii) used improper testing techniques, (iii) manipulated testing methodology, (iv) abandoned undesirable test results, (v) falsified test data, (vi) failed to adequately investigate and report the diminished efficacy of its mumps vaccine, (vii) falsely verified that each manufacturing lot of mumps vaccine would be as effective as identified in the labeling, (viii) falsely certified the accuracy of applications filed with the FDA, (ix) falsely certified compliance with the terms of the CDC purchase contract, (x) engaged in the fraud and concealment described herein for the purpose of illegally monopolizing the U.S. market for mumps vaccine, (xi) mislabeled, misbranded and falsely certified its mumps vaccine, and (xii) engaged in the other acts described herein to conceal the diminished efficacy in the vaccine the government was purchasing. Merck engaged in all of this misconduct to maintain its monopoly

of the U.S. market for mumps vaccines and to secure continued payment by the government of Merck's false or fraudulent claims for its sales of the mumps vaccine.

155. In addition, at least for false or fraudulent claims pending or made on or after June 7, 2008, Merck violated 31 U.S.C. § 3729(a)(1)(B) (formally 31 U.S.C. § 3729(a)(2) as amended by the Fraud Enforcement and Recovery Act of 2009) when Merck knowingly made, used, or caused to be made or used, false records or statements material to its false or fraudulent claims when Merck, among others things: (i) failed to disclose that its mumps vaccine was not as effective as Merck represented, (ii) used improper testing techniques, (iii) manipulated testing methodology, (iv) abandoned undesirable test results, (v) falsified test data, (vi) failed to adequately investigate and report the diminished efficacy of its mumps vaccine, (vii) falsely verified that each manufacturing lot of mumps vaccine would be as effective as identified in the labeling, (viii) falsely certified the accuracy of applications filed with the FDA, (ix) falsely certified compliance with the terms of the CDC purchase contract, (x) engaged in the fraud and concealment described herein for the purpose of illegally monopolizing the U.S. market for mumps vaccine, (xi) mislabeled, misbranded, and falsely certified its mumps vaccine, and (xii) engaged in the other acts described herein to conceal the diminished efficacy of the vaccine the government was purchasing.

156. These false statements, records, and data, and Merck's multiple failures to comply with its various duties of disclosure, investigation, testing and reporting, were material to the government's purchases of and payments for Merck's vaccine, and the CDC's long-standing recommendation to have the public vaccinated with Merck's mumps vaccine. This materiality is reflected in:

- Merck's contractual and statutory duties to disclose to the government all information regarding the safety and efficacy of its mumps vaccine;
- Merck's multiple intentional violations of these duties;
- The CDC's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The FDA's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The National Vaccine Program's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The CDC's responsibility to provide health care professionals and the public with accurate and up-to-date information on the safety and efficacy of vaccines;
- Merck's decision to conduct PRN testing of its mumps vaccine which would be reported to the FDA;
- Merck's abandonment of the 1999 PRN methodology in favor of a methodology that would yield better results;
- Merck's improper use of animal antibodies in its "enhanced" PRN test to artificially boost its seroconversion results;
- Merck's falsification of pre-positive test data to report the results it wanted using the animal antibodies in its testing;
- The CDC's continued belief in the face of the 2006 outbreak that there was nothing wrong with Merck's vaccine and that it should continue to be used;
- The call by at least one CDC doctor for a new vaccine if the Merck vaccine was not effective in preventing outbreaks;
- The prominent publication of inaccurate mumps efficacy information by the Immunization Action Coalition
- Merck's continuing efforts to improperly maintain its monopoly of the U.S. market for mumps vaccine through its false representation of an inflated efficacy rate; and ultimately

- Merck's own recognition that it would lose its exclusive license to sell mumps vaccine if it did not measure and report at least a 95 percent seroconversion rate in the mumps efficacy testing conducted in Krah's lab under Protocol 007.

157. Each representation Merck made to the government asserting that its mumps vaccine was at least 95 percent effective, including through its product package inserts, the reporting of its fabricated test results, and otherwise, as described above, constituted a false statement or record. Likewise, each invoice Merck submitted, or caused to be submitted, to the government for payment for the purchase of the vaccines, constituted a false or fraudulent claim for payment. Relators cannot identify at this time all of the false claims for payment caused by Merck's unlawful conduct because they were submitted at numerous times under various requests between 2000 and the present.

158. To the extent that the facts alleged in this Complaint have been previously disclosed to the public or the government in any fashion, Relators are each an "original source" of the information as defined in 31 U.S.C. § 3730(e)(4).

159. The United States government, the public, and the public treasury have been damaged by and continue to be damaged by Merck's fraudulent conduct.

160. In addition, Merck's fraudulent conduct may be in violation of a 2008 Corporate Integrity Agreement that Merck entered into with the Office of Inspector General of the Department of Health and Human Services. Merck entered into this agreement as part of its settlement with the United States to resolve prior unrelated False Claims Act litigation. As part of this agreement, Merck is obligated to promote its "products (including vaccines) that are reimbursed by Federal health care programs" in compliance with the federal program requirements.

PRAYER FOR RELIEF

Wherefore Relators requests the following relief:

A. That Merck cease and desist from violating 31 U.S.C. § 3729, *et seq.*;

B. That the Court enter judgment against Merck in an amount equal to three times the damages suffered by the United States due to Merck's unlawful conduct;

C. That the Court enter judgment against Merck assessing a civil penalty of no less than $5,500 and no more than $11,000 for each violation of 31 U.S.C. § 3729;

D. That Relators receive the maximum award allowed by 31 U.S.C. § 3730(d);

E. That Relators be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d);

F. That the Court award pre and post-judgment interest on any damages awarded to the United States or Relators; and

G. That the United States and Relators be awarded all such other relief that the Court deems just and proper.

JURY DEMAND

Relators hereby demand a trial by jury.

Dated: April 27, 2012

Keller Grover LLP

Jeffrey F. Keller
Kathleen R. Scanlan
1965 Market Street
San Francisco, CA 94103
Tel. (415) 543-1305
Fax (415) 543-7861

Meredith & Associates

Joel Meredith with permission by KRS
Joel C. Meredith
1521 Locust Street, 8th Floor
Philadelphia, PA. 19102
Tel: 215-564-5182
Fax: 215-569-0958

Wasserman, Comden, Casselman & Esensten, L.L.P.

Melissa Harnett
5567 Reseda Blvd.
Suite 330
Tarzana, CA 91356
Tel: (818) 705-6800
Fax: (818) 345-0162

Constantine Cannon LLP

Gordon Schnell
Jeffrey I. Shinder
Jason Enzler
Marlene Koury
335 Madison Ave.
New York, NY 10017
Tel: (212) 350-2700
Fax: (212) 350-2701

Schlam Stone & Dolan LLP

Robert L. Begleiter
26 Broadway, 19th Floor
New York, NY 10004
Tel: (212) 344-5400
Fax: (212) 344-7677

Counsel for Relators
Stephen A. Krahling
Joan A. Wlochowski

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* STEPHEN A. KRAHLING AND JOAN A. WLOCHOWSKI,	:	CIVIL ACTION
Relators,	:	NO. 10-4374 & NO. 12-3555
v.	:	
MERCK & CO., INC.,	:	
Defendant.	:	

AMENDED MEMORANDUM

Jones, II, J. **September 5, 2014**

In Civil Action No. 10-4374, Relators Stephen A. Krahling and Joan A. Wlochowski ("Plaintiffs") bring this *qui tam* action in accordance with the False Claims Act ("FCA"), pursuant to 31 U.S.C. §§ 3729-33. Relators allege that their former employer, Defendant Merck & Co., Inc. ("Merck") fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine in violation of the FCA. The United States declined to intervene in this action, filing a Notice of Election to Decline Intervention before this Court on April 27, 2012. (Dkt. No. 14). Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a)and 9(b). (Dkt. No. 45).

In Civil Action No. 12-3555, Chatom Primary Care, P.C., Andrew Klein, M.D., John I. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No.

26.) Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). (Dkt. No. 40).

For purposes of deciding the Motions to Dismiss, this memorandum takes as true facts as alleged in the Amended Complaints. *See Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). For the reasons that follow, Defendant's Motions regarding all claims for both cases are granted in part and denied in part.

I. BACKGROUND

A. The Parties

Stephen A. Krahling and Joan A. Wlochowski (the "Relators") bring this *qui tam* action against Merck & Co., Inc. ("Defendant"). Relators were employed as virologists in the Merck lab and allegedly witnessed first-hand the allegedly fraudulent efficacy testing. (Dkt. No. 12 ¶ 3, 8-9.)

Chatom Primary Care, P.C., Andrew Klein, M.D., John I. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No. 26.)

Defendant is a New Jersey corporation with its vaccine division based in West Point, Pennsylvania. (Dkt. No. 12 ¶ 10.) Defendant is the sole manufacturer licensed by the FDA to sell Mumps Vaccine (M-MR®II and ProQuad®) ("Mumps Vaccine") in the United States. (Dkt. No. 12 ¶ 11.)

B. Relators' and Plaintiffs' Alleged Facts

The Court recites the facts in the light most favorable to the nonmoving parties and draws all reasonable inferences in their favor. According to Relators' Amended Complaint, in 1999, Defendant initiated new efficacy testing of its Mumps Vaccine. (Dkt. No. 12 ¶¶ 22, 25.) Relators allege that Defendant first tested their vaccine with a Mumps Plaque Reduction Neutralization assay comparing pre and post vaccinated blood to test whether the vaccine neutralized the virus. (Dkt. No. 12 ¶ 25-29). Relators note that rather than using the "gold standard" approach and testing the vaccine against a "wild-type mumps virus," Defendant tested it against the attenuated

virus strain that had created the vaccine in the 1960s. (Dkt. No. 12 ¶ 29). Relators allege that comparing a vaccine to its originator virus strain would likely overstate the vaccine's effectiveness. (Dkt. No. 12 ¶ 29.) According to the Amended Complaint, the results of this first test did not result in the "desired 95 percent threshold," so Defendant abandoned this methodology in subsequent tests. (Dkt. No. 12 ¶¶ 30-32.)

Defendant created a second testing methodology: Enhanced Mumps Plaque Reduction Neutralization Assay. (Dkt. No. 12 ¶ 33.) Defendant allegedly told Relators that the "objective" of this new methodology was to "[i]dentify a mumps neutralization assay format…that permits measurement of a ≥ 95% seroconversion rate in MMR®II vaccines." (Dkt. No. 12 ¶ 34.) Defendant continued to test the vaccine against the virus strain that originated the vaccine. (Dkt. No. 12 ¶ 35.) In addition, Defendant added animal antibodies to pre and post vaccinated blood samples. (Dkt. No. 12 ¶ 35.) Relators allege that this addition was "for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the lab." (Dkt. No. 12 ¶¶ 35-39.) Relators claim that the use of animal antibodies created a high number of pre-vaccinated positive results, which Defendant systemically destroyed or falsified in order to legitimize the use of animal antibodies. (Dkt. No. 12 ¶¶ 40-51.) Relators also allege that senior management was aware, complicit, and in charge of this testing. (Dkt. No. 12 ¶¶ 52-58.)

Relators reported these alleged infractions to the FDA, leading to an FDA visit. (Dkt. No. 12 ¶¶ 59-64.) After the FDA visit, Relators were barred from participating in the mumps vaccine testing. (Dkt. No. 12 ¶ 66.) Relators assert that Defendant continued to make the false representations of its inflated 95 percent efficacy rate to the government, while deliberately covering up the results of the tests showing a diminished efficacy.

C. Relators' Allegations

Relators allege two overall counts of violations of the FCA. First, Plaintiffs allege that Defendant billed the CDC for purchase of its mump vaccines when Defendant knew of the vaccine's diminished efficacy. (Dkt. No. 12 ¶ 152.) Plaintiffs' theory is that because the vaccine's efficacy was diminished, the vaccine was mislabeled and was not the product for which the government paid. (Dkt. No. 12 ¶ 152.) As such, Plaintiffs allege that Defendant knowingly presented a fraudulent claim for payment to the U.S. government in violation of 31 U.S.C. § 3729(a)(1)(A).

Second, Plaintiffs allege that Defendant falsified, abandoned, and manipulated testing data that should have been shared with the government in order to fraudulently mislead the government into purchasing the mumps vaccine. (Dkt. No. 12 ¶ 155.) As such, Plaintiffs allege that Defendant knowingly incorporated falsified records material to their fraudulent claims for payment for the vaccine. 31 U.S.C. § 3729(a)(1)(B).[1]

D. Plaintiffs' Allegations

Plaintiffs based their Complaint on the *qui tam* action filed by the Relators. (Dkt. No. 26, p. 5.) Based on the same allegations, Plaintiffs allege that Defendant's manipulation and misrepresentation of the seroconversion rate of the Mumps Vaccine to the United States government , led to Defendant's monopoly of the relevant market in violation of the Sherman Act and violations of various state laws. Plaintiffs allege six counts:

1. **Count I**: Monopolization in violation of the Sherman Act. 15 U.S.C. § 2. (Dkt. No. 26 ¶¶ 151-55.) In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt.

[1] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market. (Dkt. No. 26 ¶ 154.)

2. **Count II**: Violation of state consumer protection laws in twenty-four states. (Dkt. No. 26 ¶ 156-69.) Plaintiffs state that Defendant engaged in false or deceptive conduct in making statements about the efficacy of the Mumps Vaccine with the intention of misleading consumers. (Dkt. No. 26 ¶¶ 163-66.)

3. **Count III**: Breach of contract. (Dkt. No. 26 ¶¶ 170-75.) Plaintiffs allege that Defendant entered a contract to provide Mump Vaccine to Plaintiffs and the Class and that part of this standardized contract included the falsified representation of the inflated efficacy rate. (Dkt. No. ¶¶ 171-74.) Plaintiffs allege suffering for the purchase price they paid for the Mumps Vaccine because of this alleged breach of contract. (Dkt. No. ¶ 174.)

4. **Count IV**: Violation of Pennsylvania's Express Warranty Law. Pa. Stat. Ann. Tit. 13 § 2313. (Dkt. No. 26 ¶¶ 176-87.) Plaintiffs allege that Defendant acted as a Merchant under the Pennsylvania Uniform Commercial Code, made a contract with Plaintiffs and class members to sell the Mumps Vaccine. (Dkt. No. 26 ¶¶ 177-80.) Plaintiffs allege that because the vaccine did not have an efficacy rate of 95, as represented by Defendant, Defendant breached an express warranty. (Dkt. No. 26 ¶¶ 181-87.)

5. **Count V**: Violation of Pennsylvania's Implied Warranty Law. Pa. Stat. Ann. Tit. 13 § 2315. (Dkt. No. 26 ¶¶ 188-97.) Plaintiffs allege that Defendant violated the warrant of merchantability at the time of the Mumps Vaccine's sale to Plaintiffs because the Vaccine was not 95 percent efficacious as represented by Defendant. (Dkt. No. 26 ¶¶ 188-97.)

6. **Count VI**: Unjust enrichment. (Dkt. No. 26 ¶¶ 198-205.) Plaintiffs allege that Defendant has benefitted financially because of its "deceptive and wrongful conduct" in misrepresenting the efficacy of the Mumps Vaccine at the expense of Plaintiffs. (Dkt. No. 26 ¶¶ 199-203.) Plaintiffs request compensatory and punitive damage. (Dkt. No. 26 ¶ 204.)

E. Procedural Posture

Relators first filed this Complaint under seal on August 27, 2010. (Dkt. No. 20.) The Compliant, docket entries, and related filings were kept under seal until June 20, 2012 during the period to intervene requested by the United States. On April 27, 2012, the United States declined to intervene in the Relators' case. (Dkt. No. 54 at 3.) Relators filed an amended complaint and

request for jury trial on April 27, 2012, unsealed on June 21, 2012. (Dkt. No. 12.) The original, unredacted complaint remains under seal. On August 31, 2012, Defendant moved to dismiss Relators' Amended Complaint with prejudice. (Dkt. No. 45.)

On September 20, 2012, Plaintiffs filed a Consolidated Amended Class Action Complaint against Defendant. (Dkt. No. 26.)

II. LEGAL STANDARDS

This Court has jurisdiction pursuant to 28 U.S. § 1331 and 31 U.S.C. § 3732(a).

A. 12(b)(6)

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief. *Id*. (internal quotation and citation omitted). Complaints that contain only "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v*. *Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. 544, 555 (2007)). The facts must demonstrate that the Plaintiff is entitled to relief, not just show a "mere possibility of misconduct." *Fowler v*. *UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (quoting *Iqbal* at 679). This standard asks that the complaint "'state a claim to relief that is plausible on its face.'" *Ashcroft v*. *Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atl*. *Corp*. *v*. *Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of

entitlement to relief.'" *Iqbal*, 556 U.S. at 679 (quoting *Twombly*, 550 U.S. at 557). In *Ashcroft v. Iqbal*, the Supreme Court clarified that this standard applies to all civil cases. *Iqbal*, 129 S. Ct. at 1949.

When deciding a motion to dismiss under 12(b)(6), the "court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). Assessing the sufficiency of a complaint is "a context-dependent exercise" because "[s]ome claims require more factual explication than others to state a plausible claim for relief." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (cited in *United States ex rel. Galmines v. Novartis Pharms. Corp.*, 2013 U.S. Dist. LEXIS 120672 (E.D. Pa. Aug. 23, 2013)) (citations omitted).

B. 9 (b)

Fed. R. Civ. P. 9(b) states "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed .R. Civ. P. 9(b). The aim of this heightened pleading standard is "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984). This standard "requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background . . . that is, the who, what, when, where and how of the events at issue." *United States of America ex rel. Ronald J. Streck v.*

Allergan, Inc., 894 F. Supp.2d 584, 601 (E.D. Pa. 2012) (citing *In re Rockefeller Ctr*. *Props*., *Inc*. *Sec*. *Litig*., 311 F.3d 198, 217 (3d Cir. 2002)).[2]

III. DISCUSSION

Defendants seek dismissal pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) on the grounds that Relators have failed to plead fraud with the requisite particularity and failed to state a claim upon which relief can be granted.

A. Relators' Claims (Case No. 10-4374)

Relators make out two counts for violations of the FCA. Relators' Complaint alleges that Defendants submitted test results to the government that contained falsifications, or omissions, of

[2] In some False Claims Act (FCA) cases, the Third Circuit has generally sought to relax this pleading standard, explaining that Relators need not "plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *U.S. ex rel. John Underwood v. Genentech, Inc*., 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010) (quoting *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir.1998)); *see also City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998) (citations omitted), *abrogation on other grounds recognized*, *Forbes v. Eagleson*, 228 F.3d 471 (3d Cir. 2000).

In other FCA cases, however, the Third Circuit has cited approvingly – but has not formally adopted –the heightened standard used by the Eleventh Circuit whereby a Relator cannot "describe a private scheme in detail" and then allege fraud simply by assuming that "requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Quinn v. Omnicare, Inc*., 382 F.3d 432, 439-40 (3d Cir.2004) (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc*., 290 F.3d 1301, 1311 (11th Cir. 2002)). The District Courts within the Third Circuit have been split on this issue with some courts dismissing complaints that do not refer to a specific false claim for payment and others allowing more general complaints to proceed. *See Underwood*, 720 F. Supp. 2d at 677 (citing *United States ex rel. Bartlett v. Tyrone Hosp., Inc*., 234 F.R.D. 113, 120 (W.D. Pa. 2006); and *United States ex rel. Schmidt v. Zimmer, Inc*., No. 00-1044, 2005 U.S. Dist. LEXIS 15648, at *1, *7-*8 (E.D. Pa. July 29, 2005) for granting dismissals; and *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186, 2006 U.S. Dist. LEXIS 65268 (W.D. Pa. Sept. 13, 2006); *United States ex rel. Landsberg v. Levinson*, No. 03-1429, 2006 U.S. Dist. LEXIS 66689 (W.D. Pa. 2006); *Gibbons ex rel. United States v. Kvaerner Phila. Shipyard, Inc*., No. 05-685, 2006 U.S. Dist. LEXIS 5172 (E.D. Pa. Feb. 10, 2006) for denying dismissals.). Looking at other circuits, however, the Eastern District of Pennsylvania has noted that the availability of evidence of fraud from the Government, as opposed to evidence being solely in the hands of the Defendant is a crucial factor in determining whether an FCA complaint should contain evidence of an actual claim in order to survive Rule 9(b). *See Underwood*, 720 F. Supp. 2d at 677; *United States ex rel. Streck v. Allergan, Inc*., 894 F. Supp. 2d 584, *601 (E.D. Pa. July 3, 2012).

relevant testing data. These omissions and falsifications were reflected in their labeling, their submissions for approvals, and their requests for payment for purchase of the medications.

Defendant argues that the Relators' claim is dependent upon a finding that the MMR Product label is false, representing a 95 percent efficacy rate. (Dkt. No. 45 at 13.) Defendant alleges that labeling changes are solely within the purview of the FDA and that the FCA is not an avenue to dispute inaccurate labeling. Plaintiffs counter that their Complaint alleged more than a false labeling issue. Rather, Relators argue that it alleged that Defendant violated multiple duties to the government across multiple instances of reports and claims that failed to disclose the veracity of testing results and that deliberately obfuscated information about the vaccine's lessening efficacy.

a. FCA in General

Count One of the Complaint alleges a violation of § 3729(a)(1)(A) of the FCA, and Count Two alleges violations of § 3729(a)(1)(B).[3] (Compl. ¶¶ 152-55.) These sections of the statute impose liability on:

> [A]ny person who--
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a)(1). Moreover, the FCA defines "knowingly" as when a defendant

> (1) has actual knowledge of the information;
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
> (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b).

[3] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

To establish a claim under § 3729(a)(1)(A) of the FCA, a relator "must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.* ("*Zimmer I*"), 386 F.3d 235, 242 (3d Cir. 2004)) (referring to previous codification of the statute as § 3729(a)(1)).

Section 3729(a)(2)(B) differs in that "liability is premised on the presentation of a 'false record or statement to get a false or fraudulent claim paid or approved.'" *Id.* at 306-07 (quoting *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000)) (referring to statute as 3729(a)(2), its previous codification). In contrast, "section 3729(a)(1)[(A)] requires only that a claimant present a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.'" *Id.* Thus § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement. *See id.*

Based on this interpretation, the Third Circuit decided in *Wilkins* that "there are two categories of false claims under the FCA: a factually false claim and a legally false claim." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (quoting *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is a condition for government payment. A legally false FCA claim is based on a 'false certification' theory of liability." *Id.*

(citing *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 129 S. Ct. 2230, 173 L. Ed. 2d 1255 (2009)).

Within the theory of false certification, there are two further categories: express and implied false certification. *See id.* A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment. *See id.* An FCA violation occurs under implied false certification when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that affect its eligibility for payment. *See id.* For a relator to succeed under this theory, the Third Circuit has required relators to show "that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Id.* at 307.

b. FCA Liability

The Court finds that the fraud-on-the-FDA theory under the FCA withstands the motion to dismiss. The *qui tam* provision states that "[a] person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government." *Id.* § 3730(b).

In memoranda in support of Defendant's motion to dismiss, Defendant argued that "with the government having declined to intervene, if Relators' case is to enforce, or restrain violations of the FDCA, it is foreclosed by 21 U.S.C. § 337(a)." (Dkt. No. 45-1 at 18.) Specifically, Defendant points the Court to Section 337(a) of the Federal Food, Drug, and Cosmetic Act ("the

FDCA") which states that "proceedings for the enforcement, or to restrain violation, of [the FDCA] *shall be by* and in the name of the United States." § 337(a).

First, Defendant argues that Relators' claims fall under the purview of the FDCA. Defendant argues Relators' claims rest on a finding that the vaccine label is misbranded, a determination which should fall squarely under the "scientific expertise" and "regulatory discretion" of the FDA under the FDCA. (Dkt. No. 45-1 at 16.) Defendant further claims that because Relators argued their version of facts to the FDA during the FDA investigation, the FDA was apprised of all the facts they allege. (Dkt. No. 45 at 4.) The theory follows: the FDA could have started an enforcement action to change the label, or to reprimand Defendant for its behavior, but it chose not to – a decision which should not be reviewed through a FCA claim. 21 U.S.C. § 331 *et seq*. As such – the argument goes - the subsequent failure of the government to intervene means that this *qui tam* action fails to be "by and in the name of the United States" under the FDCA.

Defendant relies on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, Plaintiffs, who claimed injuries resulting from the use of orthopedic bone screws in the pedicles of their spines, alleged that the Defendant, a consulting company working for the bone screw manufacturer, made fraudulent representations to the FDA to secure FDA approval. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001). The Court held that "plaintiffs' state-law fraud-on-the-FDA claims" were pre-empted by the Medical Device Amendment to the Federal Food, Drug, and Cosmetic Act and the FDA's regulatory scheme, and discretion, to enforce the Act. *Buckman*, 531 U.S. at 348. The Court held that "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently

with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350. This case is easily distinguishable. The Plaintiffs in *Buckman* sought relief under state tort law, not the FCA. *Buckman*, 531 U.S. at 343.

The United States Government filed a Statement of Interest, clarifying that, from their perspective, "Holding that only the Government, and not a relator, can litigate a False Claims Act suit arising from allegations of fraud on the FDA or conduct in violation of FDA regulations would be inconsistent with the purposes of the False Claims Act." (Dkt. No. 54 at 5.) "The fact that a False Claims Act case may involve omissions to regulatory agencies, discretion in agency action, or violations of regulations does not preclude the action from proceeding." (Dkt. No. 54 at 7.) The Court agrees. Relators allege that Defendant consistently and deliberately withheld pertinent information as to the safety and efficacy of a medication from the government. It is this alleged omission that is the grounds for FCA liability.

c. Relators' § 3729(a)(1)(A) Claim Withstands 12(b)(6) and 9(b)

Under § 3729(a)(1)(A), Relators must allege with sufficient particularity that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel*. *Wilkins*, 659 F.3d at 304-05 (internal citations omitted).

i. **Defendants Submitted Claims to the Government**

For an FCA complaint to survive a 12(b)(6) motion under an implied false certification theory, a relator does not need to produce a specific instance of a false claim. *Id*. at 308 ("We never have held that a plaintiff must identify a specific claim for payment at the pleading stage of

the case to state a claim for relief."). In *Wilkins*, the Third Circuit noted that such a requirement may exist under 9(b), but chose not to rule on that question in this opinion. *Id*. As such, under the Third Circuit's current jurisprudence, the Court finds that Relators' Complaint survives the heightened pleading requirement of 9(b). [4] Relators plainly allege that Defendant submitted claims for payment to the government for the government's purchase of the vaccine on many occasions between 1999 and the present, following the allegedly fraudulent testing. ¶¶ 4, 144-45, 147-49, 152-55.

ii. **Claims Were False**

[4] Defendant pointed the Court to two out-of-circuit cases of which the Court took particular note. (*See* Def. Mot. to Dismiss, Dkt. No. 45-1 at 32-33, 36.) The Court found these cases instructive, but not persuasive.

In *United States ex rel*. *Tessitore*, the Court held that the Complaint (1) failed to include a date that any application was submitted to the FDA; (2) failed to identify who at Defendant's company made the allegedly false statements to the FDA and who was involved in the concealment scheme; (3) failed to allege any of the actual content of these submissions. *United States ex rel*. *Tessitore v*. *Infomedics, Inc*., 847 F. Supp. 2d 256, 265 (D. Mass 2012). In *United States ex rel*. *Tessitore,* the specific dates of the claims was of particular relevance because the alleged adverse event reports arguably occurred after the claims were submitted, rendering Relator's fraud claims moot. In contrast, in this case, it is undisputed that claims were absolutely made after the allegedly fraudulent testing. The timing is of less relevance to the validity of Relators' claims.

Second, in *United States ex rel*. *Provuncher v*. *Angioscore*, Plaintiff/relator, a former employee of Defendant, a biotechnology firm that manufactures and distributes angioplasty catheters, brought this "whistle blower" action based on allegations that Defendant "deliberately suppressed adverse event reporting of injuries and incidents" and sold the product knowing that it was "defective" in violation of the federal False Claims Act (the "FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B). No. 09-12176, 2012 WL 3144885, at *1 (D. Mass. 2012). Plaintiff filed a Second Amended Complaint that provided additional details, but maintained the same - and what the Court considered, the flawed – theory that there had been a violation of the FCA because there was evidence of a small error rate for the device that was not allegedly shared with the FDA. *Id*. at *1. The Court held that this theory failed to plead a violation of the FCA because, even accepting all of Plaintiff's facts as true, Plaintiff had only alleged a failure rate for the medical device for which there was already an expectation of a similar error rate. *Id*. The Court held that this was "not the evil that Congress sought to root out by passage of the False Claims Act." *Id*. The Court notes that the facts alleged in this case are distinct. In this case, Relators do not allege solely that there was a failure to report an error rate similar to one already anticipated for the vaccine. Rather, Relators allege that Defendant withheld from the government, in violation of statutory and contractual duties, information about their testing methodology and results of lessened efficacy below what was already anticipated or expected by the government.

In conclusion, the Court takes note of these cases but does not find that such specificity is required at this stage. The Court notes Defendants' argument that the current allegations fail to specify dates of submissions, how the reports were submitted, to whom specifically these reports were directed, etc. (Def. Mot. to Dismiss, Dkt. No. 45-1 at 31.) At this stage, the Court finds that these unknowns are not fatal to Relators' claims. Discovery will help to elucidate these specificities further.

Relators have sufficiently pled that there was information about the alleged lessened efficacy of the vaccine that was not shared with the government and that the omission of this information was material to the government continuing to purchase the vaccines. Relators also pled a theory of liability that the claims were "legally false." (Rel. Opp. to MTD, Dkt. No. 47 at 23-24.) Relators and Plaintiffs' allege that Defendants have a general duty to federal officials, 18 U.S.C. § 1001, a contractual and statutory duty to provide the CDC with accurate information regarding safety and efficacy of the vaccine, (Dkt. No. 12 ¶¶ 105-11), duties to the FDA under the Public Health Service Act, the Food Drug and Cosmetics Act, and FDA regulations, 21 U.S.C. § 301 *et seq*.; 42 U.S.C § 262 *et seq*.; 21 C.F.R. § 600.12(b); 21 C.F.R. § 210 *et seq*., and duties to the National Vaccine Program and the Vaccine Injury Compensation Program. (Dkt. No. 12 ¶¶118-19.) Relators argue that Defendant's duties to report the diminished efficacy were triggered when Defendant learned of the results of its testing no later than 1999. (Dkt. No. 12 ¶ 122.) Relators allege that Defendant's "duty to disclose accurate and current information of the efficacy were not merely a condition of payment for" Defendant but also a "condition for [Defendant]'s ability to sell the vaccine at all." (Dkt. No. 47 at 23.)

In the Complaint, Relators further allege that:

- Defendant has a duty to disclose diminished efficacy to the FDA. 21 C.F.R. § 600.12(b). (Dkt. No. 12 ¶ ¶ 114-16.)
- Defendant has a duty to manufacture vaccines in conformance with cGMP. 21 C.F.R. § 210.2. Manufacturers are required to test for safety, purity, and potency of every lot of the vaccine to be sold. 21 C.F.R. § 610. If a manufacturer learns of a deviation from the specifications, it has a duty to disclose that information to the FDA, fully investigate it, and correct it. 21 C.F.R. § 600.14; 21 U.S.C. § 331(c); 21 C.F.R.§ 211.192. (Dkt. No. 12 ¶ 115.)
- Defendant has a duty to report to the FDA adverse experience events. (Dkt. No. 12 ¶ 116) (citing 21 C.F.R. § 600.80.) As a manufacturer of vaccines for pediatric population, Defendant must provide an annual report to inform the FDA of whether new studies in the pediatric population have been initiated, an analysis of

available safety and efficacy data, and an assessment of data needed to ensure appropriate labeling for the pediatric population. 21 C.F.R. § 601.28.

- Defendant has a duty to self-monitor and update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading. (Dkt. No. 12 ¶ 117.)

Taken all together, Relators argue that there were both express and implied legal duties that the claims submitted to the government not omit the alleged poor testing results. Taking these facts alleged as true, this theory survives the Motion to Dismiss.[5]

iii. Defendant Knew Claims Were False

Realtors sufficiently allege their first-hand experience in Defendants' laboratories, where they witnessed supervisors and managers instructing staff persons to withhold information from the government regarding the diminished efficacy. For the purposes of this stage of litigation, these allegations provide Defendant with sufficient notice of the claims at issue. Relators' claim alleging a violation of § 3729(a)(1)(A) is well pled.

[5] Relators also allege that the claims were "factually false" because they contain "affirmative misrepresentations to the CDC about the vaccine's efficacy" and because Defendant fraudulently omitted "all of the information it kn[e]w[] -- but [] schemed to conceal -- on the vaccine's significantly diminished efficacy." (Dkt. No. 47 at 38.) Under this theory, the claims are factually false because they contain affirmative misrepresentations due to the deliberate omission about the efficacy of the vaccine. These deliberate omissions could rise to the level of a factually false claim. The Court notes that at this point, Relators have not been able to allege any specifics as to what information was or was not included in these claims. The Court awaits the fruits of discovery for further guidance as to the strength of the "factually false" theory.

d. Relators' § 3729(a)(1)(B) Claim Withstands 12(b)(6) and 9(b)

Relators must demonstrate that Defendant (1) knowingly made, used, or caused to be made or used a false record or statement (2) material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).[6] For this claim, Relators allege that Defendant:

> failed to disclose that its mumps vaccine was not as effective as Merck represented, (ii) used improper testing techniques, (iii) manipulated testing methodology, (iv) abandoned undesirable test results, (v) falsified test data, (vi) failed to adequately investigate and report the diminished efficacy of its mumps vaccine, (vii) falsely verified that each manufacturing lot of mumps vaccine would be as effective as identified in the labeling, (viii) falsely certified the accuracy of applications filed with the FDA, (ix) falsely certified compliance with the terms of the CDC purchase contract, (x) engaged in the fraud and concealment describe herein for the purpose of illegally monopolizing the U.S. market for mumps vaccine, (xi) mislabeled, misbranded, and falsely certified its mumps vaccine, and (xii) engaged in the other acts described herein to conceal the diminished efficacy of the vaccine the government was purchasing." (Dkt. No. 12 ¶ 155.)

i. Relators sufficiently allege that Defendant knowingly used a false statement

Relators alleged in multiple instances throughout their Complaint that false statements were given to the government, including:

- False representations through package inserts. (Dkt. No. 12 ¶¶ 71-73.) Relators allege that the Mumps Vaccine's insert states a 95 percent efficacy rate which is a clear misrepresentation of the efficacy rate Defendant found in its testing starting in 1999. (Dkt. No. 12 ¶ 72-3.)
- False representations through expanded distribution of the vaccine. (Dkt. No. 12 ¶¶ 74-78.) Relators allege that Defendant falsely represented an efficacy rate of 95 percent or higher to the FDA and the EMA in order to receive approvals to sell new products incorporating the Mumps Vaccine. (*Id*.)
- False representations through Defendant's application for a labeling change on potency of MMRII. (Dkt. No. 12 ¶¶ 79-81.) Relators allege that during the labeling change process in 2007 for MMRII, Defendant did not disclose to the FDA that their internal testing revealed a diminished efficacy rate of the Mumps Vaccine. (*Id*.) Rather, Defendant continued to maintain that the Mumps Vaccine had a 95 percent efficacy rate. (Dkt. No. 12 ¶ 81.)

[6] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

- False representations through recent Mumps Outbreaks. (Dkt. No. 12 ¶¶ 82-96.) Relators allege that during the 2006 Mumps outbreak, Defendant failed to disclose to the CDC or the FDA its knowledge of the weaker efficacy of its Mumps Vaccine and continued to misrepresent the efficacy as 95 percent. (Dkt. No. 12 ¶¶ 83-91.) Similarly, during a 2009 outbreak, Defendant again continued to make false representations to the CDC and the FDA. (Dkt. No. 12 ¶¶ 92-96.)
- False representations through the Immunization Action Coalition. (Dkt. No. 12 ¶¶ 97-101.) Relators allege that Defendant made false representations to the IAC, reflected in the IAC's materials, which are sanctioned and supported by the CDC. (*Id*.)

At this stage, the Court holds that Relators have sufficiently pled facts that could demonstrate that Defendant provided a false statement to the government. Relators can support a claim under the FCA alleging that Defendant deliberately obfuscating or provided incomplete information to the FDA.

B. Plaintiffs' Claims (Case No. 12-3555)

Defendant moved to dismiss under 12(b)(6) and 9(b). (Dkt. No. 40.) Plaintiff adopts as true all of Relators' factual allegations in the Amended Complaint and alleges the following counts:

1. **Count I**: Monopolization in violation of the Sherman Act. 15 U.S.C. § 2. (Dkt. No. 26 ¶¶ 151-55.) In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt. No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market. (Dkt. No. 26 ¶ 154.)
2. **Count II**: Violation of state consumer protection laws in twenty-four states. (Dkt. No. 26 ¶ 156-69.) Plaintiffs state that Defendant engaged in false or deceptive conduct in making statements about the efficacy of the Mumps Vaccine with the intention of misleading consumers. (Dkt. No. 26 ¶¶ 163-66.)
3. **Count III**: Breach of contract. (Dkt. No. 26 ¶¶ 170-75.) Plaintiffs allege that Defendant entered a contract to provide Mump Vaccine to Plaintiffs and the Class and that part of this standardized contract included the falsified representation of the inflated efficacy rate. (Dkt. No. ¶¶ 171-74.) Plaintiffs allege suffering for the purchase price they paid for the Mumps Vaccine because of this alleged breach of contract. (Dkt. No. ¶ 174.)
4. **Count IV**: Violation of Pennsylvania's Express Warranty Law. Pa. Stat. Ann. Tit. 13 § 2313. (Dkt. No. 26 ¶¶ 176-87.) Plaintiffs allege that Defendant acted as a

Merchant under the Pennsylvania Uniform Commercial Code, made a contract with Plaintiffs and class members to sell the Mumps Vaccine. (Dkt. No. 26 ¶¶ 177-80.) Plaintiffs allege that because the vaccine did not have an efficacy rate of 95, as represented by Defendant, Defendant breached an express warranty. (Dkt. No. 26 ¶¶ 181-87.)

5. **Count V**: Violation of Pennsylvania's Implied Warranty Law. Pa. Stat. Ann. Tit. 13 § 2315. (Dkt. No. 26 ¶¶ 188-97.) Plaintiffs allege that Defendant violated the warrant of merchantability at the time of the Mumps Vaccine's sale to Plaintiffs because the Vaccine was not 95 percent efficacious as represented by Defendant. (Dkt. No. 26 ¶¶ 188-97.)
6. **Count VI**: Unjust enrichment. (Dkt. No. 26 ¶¶ 198-205.) Plaintiffs allege that Defendant has benefitted financially because of its "deceptive and wrongful conduct" in misrepresenting the efficacy of the Mumps Vaccine at the expense of Plaintiffs. (Dkt. No. 26 ¶¶ 199-203.) Plaintiffs request compensatory and punitive damage. (Dkt. No. 26 ¶ 204.)

a. Sherman Act Allegations

In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt. No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market in violation of § 2 of the Sherman Act. (Dkt. No. 26 ¶ 154.)

The Sherman Act, with its "sweeping language," makes it unlawful to "monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2.). To prove a violation of § 2 of the Sherman Act, Plaintiffs must show: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). The acquisition or possession of monopoly power must be accompanied by some anticompetitive conduct on the part of the possessor. *Verizon Commcn's Inc. v. Law Offices of*

Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007). Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) ("It is axiomatic that the antitrust laws were passed for 'the protection of *competition*, not *competitors*.'" (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962))); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.").

First, Plaintiffs have demonstrated that Defendant had monopoly power in the relevant market. Plaintiffs allege that Defendant was the sole manufacturer licensed by the FDA to sell the vaccine in the U.S. (Dkt. No. 26 ¶ 16.) This fact is not contradicted by Defendant. (Dkt. No. 40.)

Second, Plaintiffs allege that Defendant willfully maintained such monopoly power through falsifying data presented to the government, as described in greater detail in Relators' claims. (Dkt. No. 26 ¶¶ 152-55.) Plaintiffs argue that by deliberately concealing information known to Defendant about the efficacy of the vaccine, other potential entrants into the mumps vaccine market were precluded because of their presumption that the U.S. government would not create additional contracts for new vaccine products while the Defendant's vaccine had a 95% efficacy rate. The basic theory is that Defendant presented fraudulent information to the government that secured Defendant a monopoly over the market.

While a slightly novel theory of liability, at this stage, the Court finds that Plaintiff has sufficiently pled a claim of violation of the Sherman Act. The Third Circuit has held that

"'[a]nticompetitive conduct' can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.'" *LePage's Inc. v. 3M*, 324 F.3d 141, 152 (3d Cir. 2003) (quoting *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998)).

For example, in *LePage's Inc. Wireless*, the Court held that finding enough facts to support the jury's holding that 3M violated Section 2 of the Sherman Act, the Court relied on the finding that 3M engaged in "exclusionary conduct that consisted of rebate programs and exclusive dealing arrangements designed to drive LePage's and any other viable competitor" from the relevant market. *LePage's Inc. v. 3M*, 324 F.3d 141, 154 (3d Cir. 2003). In *Broadcomm Corp. v. Qualcomm Inc.*, Plaintiff alleged that Defendant monopolized a market by "by falsely promising to license its patents according to the fair, reasonable, and non-discriminatory ("FRAND") terms set by the European Telecommunications Standards Institute ("ETSI") and its standards-defining organizations ("SDO") counterparts in the United States, but then reneging on those promises after it succeeded in having its technology included in the standard." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007). The Court held that " (1) in a consensus-oriented private standard-setting environment, (2) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (3) coupled with an SDO's reliance on that promise when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct." *Broadcom Corp.*, 501 F.3d at 314.

Similarly, in this case, Plaintiffs have successfully pled a claim for a § 2 violation. Taking the facts in the light most favorable to Plaintiffs, Defendant's fraudulent misrepresentations

about Defendant's own product, coupled with the unique facts of this case (e.g., the 100% monopoly of the market and the arguable statutory and contractual duties to disclose information) create the basis for an antitrust claim that Defendant willfully maintained monopoly power through exclusionary tactics.[7] Plaintiffs have argued sufficient facts to sustain a claim for proximate causation, detailing the significant barriers that other companies would face to enter the Mumps vaccine market. (Dkt. No. 26 ¶ 30.)

b. State law claims

Plaintiffs have only stated claims under N.Y. Gen. Bus. Law § 349(a) (McKinney 2014) and N.J. Stat. Ann. § 56:8-2 (West 2014). In reaching this decision, the Court first considers the threshold issues of Article III standing and preemption, before considering whether Plaintiffs' surviving claims have been adequately stated under Fed. R. Civ. P. 12(b)(6) and 9(b).

i. Standing

Initially, the Court must decide whether Defendant's challenge to Plaintiffs' Article III standing is timely. This Court finds that the challenge is appropriate with respect to the *named Plaintiffs*, consistent with Supreme Court and Third Circuit precedent, and decisions reached by courts in the Eastern District of Pennsylvania,

[7] Defendant points the Court to *Oce North America, Inc. v. MCS Services, Inc.*, 795 F. Supp. 2d 337 (D. Md. 2011). The Court finds that case distinguishable as it surrounded a claim that a company had made false and misleading statements about a competitor's company; which is not at issue in this case. *Id.* at 341. Similarly, the Court distinguishes Third Circuit precedent *Santana Products, Inc. v. Bobrick Washroom Equip., Inc.*, as that case was about Section One of the Sherman Act and concerned Defendants' alleged fraudulent statements about a competitor's product. 401 F.3d 123, 134-35 (3d Cir. 2005). Moreover, in *Santana*, the allegedly fraudulent statements were made to denigrate a competitor's product so that the government would choose Defendants' product instead for the building of a specific project. *Id.* at 133. The Court stressed that despite the fraudulent statements, there was no exclusion in the overall market in a "real sense" because Plaintiff, competitor company to Defendant, "was still free to sell its products and consumers were free to buy them." *Id.* Defendant's further comparison to *Schachar v. Am. Acad. of Ophthalmology, Inc.*, is also not a great comparator as it was solely about a § 1 claim and about comments about competitors. 870 F.2d 397, 399 (7th Cir. 1989).

Plaintiffs cite *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), and a series of lower court cases interpreting *Ortiz*, to support their assertion that this Court should defer ruling on Article III standing until after class certification. (Dkt. No. 43 at 27) (citing *In re Chocolate Antitrust Litig.*, 602 F. Supp. 2d 538 (M.D. Pa. 2009); *Clark v. McDonald's Corp.*, 213 F.R.D. 198 (D.N.J. 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

However, *Ortiz* is unavailing. In that case, the Supreme Court considered the timeliness of petitioners' argument that members of the putative class lacked Article III standing. *Ortiz*, 525 U.S. at 830. The Court resolved this issue by holding that certification may precede standing analysis where the former is "logically antecedent" to the latter. *Id*. Because no class had been certified, petitioners' challenge would have forced the Court to rule on the standing of persons not yet before the Court. Thus, determining the existence of a class at all logically preceded evaluating whether potential class members had proper standing.

This Court is not persuaded that the exception in *Ortiz* controls in the instant case. The Defendant does not challenge the definition of the class, or the standing of the members of the putative class. Rather, the Defendant challenges the *named Plaintiff's* standing. (Mot. Dismiss 22.) Thus, the Defendant has not asked the Court to consider the standing of persons not part of the suit, but persons, by definition, already before the Court. Because the *Ortiz* exception is inapplicable, Supreme Court precedent affirming standing as a threshold jurisdictional matter remains controlling. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94-95 (1998) (citing *Ex parte McCardle*, 7 Wall. 506, 514 (1868) ("Without jurisdiction the court cannot proceed at all in any cause."); *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 490 (1982) ("A plaintiff's standing is a

jurisdictional matter for Art. III courts, and thus a 'threshold question' to be resolved before turning attention to more 'substantive' issues.") (Brennan, J., dissenting).

This narrow interpretation of *Ortiz* is not novel. In *In re Wellbutrin XL Antitrust Litig*., the court faced the same legal question. 260 F.R.D. 143, 167 (E.D. Pa. 2009). Like Plaintiffs here, plaintiffs in *Wellbutrin* argued that the holding in *Ortiz* permitted the District Court to delay standing analysis until after class certification. *Id*. Rejecting that argument, the court concluded that *Ortiz* did nothing to disturb settled precedent that, with respect to named plaintiffs, standing remained a threshold issue. *Id*. at 155 (asserting that the "unique posture" of *Ortiz* and its silence concerning standing requirements of named plaintiffs "demonstrate that a standing analysis should not be deferred."). "A ruling as to the *named plaintiffs'* standing depends in no way upon the standing of *proposed class members*. Thus, the named plaintiffs' standing is not 'logically antecedent' to the issue of class certification." *Id*. (emphasis added). Thus, the court found that it was free to rule on the defendant's standing challenge before certifying a class.

This Court's narrow reading of *Ortiz* is also consistent with Third Circuit precedent, which holds that a named plaintiff must establish proper standing to bring each claim before class certification. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action,* 678 F.3d 235, 245 (3d Cir. 2012) ("A plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press.") (internal citation omitted); *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007) ("The initial inquiry [in a class action] … is whether the lead plaintiff individually has standing, not whether or not other class members have standing."); *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 306-207 (3d Cir. 1998) (" [W]hether an action presents a 'case or controversy' under Article III is

determined vis-à-vis the named parties."); *Zimmerman v. HBO Affiliates*, 834 F.2d 1163, 1169 (3d Cir. 1987) ("It is well settled that to be a class representative on a particular claim, the plaintiff must himself have a cause of action on that claim.").

Plaintiffs argue that their position is supported by a "nearly unbroken line of precedent" supporting its position from the Second Circuit, the District of New Jersey, and the Middle District of Pennsylvania. (Opp'n 30-31.) However, Plaintiffs' assertion ignores Eastern District cases that have rejected arguments nearly identical to the one made here. *See In re Processed Egg Prods. Antitrust Litig.*, 851 F.Supp.2d 867, 882 (E.D. Pa. 2012) ("…[T]here is an apparent consensus that the Court may consider the standing of the *named plaintiff's"* before deciding to certify a class) (emphasis in original); *Sheet Metal Workers 441 Health & Welfare Plan v. GlaxoSmithKline*, 263 F.R.D. 205, 210 (E.D. Pa. 2009) ("…[W]hen the *named plaintiff* lacks a cause of action, the Court should dismiss the action before proceeding to class certification.") (emphasis added); *In re Flonase Antitrust Litig.*, 610 F.Supp.2d 409, 414 (E.D. Pa. 2009) ("It would not be premature…to first determine if Plaintiffs have stated a claim…because at least one named Plaintiff must have a cause of action on a claim for that claim to survive a motion to dismiss."). Moreover, Plaintiffs ignore cases from the Fifth and Ninth Circuits that construe *Ortiz* narrowly. *See Easter v. Am. West Fin.*, 381 F.3d 948, 962 (9th Cir. 2004) (*Ortiz "*does not require courts to consider class certification before standing."); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir. 2002) (holding that the District Court erred by not demanding plaintiffs show standing before certifying a class).

In light of the forgoing, the Court deems the Defendant's challenge ripe for decision, and will therefore conduct a standing analysis.

a) Standing: Standard of Review

The Court considers a motion to dismiss for lack of standing under Federal Rule of Civil Procedure under 12(b)(1). *Ballentine v. United States*, 486 F.3d 806, 820 (3d Cir. 2007). "When considering a motion to dismiss for lack of standing, the trial court must accept as true all material allegations in the plaintiff's complaint." *Blunt v. Lower Merion Sch. Dist.*, 559 F. Supp. 2d 548, 565 (E.D. Pa. 2008) (citing *Warth v. Seldin*, 422 U.S. 490, 501 (1975)). On a motion to dismiss for standing, the plaintiff "'bears the burden of establishing' the elements of standing." *Ballentine*, 486 F.3d at 806 (citing *FOCUS v. Allegheny Cnty. Ct. of Com. Pleas*, 75 F.3d 834, 838 (3d Cir. 1996)). However, "general factual allegations of injury resulting from the defendant's conduct may suffice." Id. (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)).

Article III standing requires a plaintiff to prove: 1) that they have suffered an injury in fact; 2) that there is a causal connection between the injury and the alleged conduct of the opposing party; and 3) that a favorable decision will likely redress the plaintiff's injury. *Edmonson v. Lincoln Nat. Life Ins. Co.*, 725 F.3d 406, 415 (3d Cir. 2013) (citing *Lujan* 405 U.S. at 560). The Court will first consider whether the Plaintiffs have met these conditions with respect to the claims based on the laws of their home states, and then with respect to the claims based on the laws of the states where they do not reside.

b) Standing: States Where Named Plaintiffs Reside

First, Plaintiffs have adequately alleged injuries-in-fact in their home states of New York, New Jersey, and Alabama. "[M]onetary harm is a classic form of injury-in-fact. Indeed it is often assumed without discussion." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286,

291 (3d Cir. 2005) (internal citations omitted). Plaintiffs assert that, as a result of Defendant's misrepresentations, they were fraudulently and deceptively induced to purchase Defendant's product and have therefore suffered an economic injury. (Dkt. No. 26 ¶ 167.) Thus, the Complaint sufficiently states a cognizable injury for Article III purposes.

Second, Plaintiffs have demonstrated a causal link between the injury and the Defendant's conduct. The injury-in-fact must be "fairly traceable" to the alleged conduct of the defendant. *Edmonson*, 725 F.3d at 415 (3d Cir. 2013) (citing *Lujan*, 504 U.S. at 560). It cannot be the result of "independent action of some third party not before the court." *Id*. Here, Plaintiffs allege that, but for the fraud and misrepresentations made by the Defendant, Plaintiffs' would not have purchased the vaccine. As a result, the plaintiffs have met their burden with respect to causation.

Third, favorable judgment by the court must be likely to provide redress to the particular injuries the plaintiffs. *Edmonson*, 725 F.3d at 415. Plaintiffs must establish a "substantial likelihood that the requested relief will remedy the alleged injury in fact." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 143 (3d Cir. 2009) (quoting Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 565, 571 (1999)). Here, Plaintiffs seek compensatory damages for the vaccine, as well as any other damages permitted by the statutes they invoke. (Dkt. 26 ¶ 169.) Both, should they be awarded, are likely to provide redress for the Plaintiffs economic injuries. Because Plaintiffs have met all three elements necessary to establish Article III standing with respect to these claims, the Court will not dismiss them for lack of standing.

c) Standing: States Where No Named Plaintiff Resides

Named Plaintiffs do not have standing to bring claims based on the laws of states in which they do not reside because they have not sufficiently pled injuries-in-fact in those states. "[N]amed plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class…." *Lewis v. Casey*, 518 U.S. 343, 357 (1996) (quoting *Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 40 n. 20 (1976)). Plaintiffs "must allege an injury to himself that is 'distinct and palpable' as distinguished from merely 'abstract,' and the alleged harm must be actual or imminent, not 'conjectural' or 'hypothetical.'" *Reilly v. Ceridian Corp.*, 664 F.3d 38, 42 (3d Cir. 2011) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)).

While the Complaint provides sufficient basis to conclude Plaintiffs were injured in their home states, the same is not true for the remaining jurisdictions. The Complaint does not specify what, if any, injuries the named Plaintiffs suffered in any of the twenty-two jurisdictions whose laws they invoke. Instead, their claims rest on abstract injuries suffered by other, unidentified members of the putative class. Therefore, they have not met their burden of proof and all claims based upon those laws must be dismissed.

As a result, Count II is dismissed with respect to all claims but those based on the laws of New York and New Jersey; Count III—which does not specify the state law on which it is based—is dismissed to the extent that it relies on the laws of states where named Plaintiffs do not reside; Count IV and Count V are dismissed in their entireties for lack of standing, as no Plaintiff resides in Pennsylvania; and, Count VI—which does not specify the state law on which it is based—is dismissed to the extent it relies on the laws of states where no named Plaintiff resides.

ii. Preemption

Defendant claims that Plaintiffs' suit is a private fraud-on-the-Food & Drug Administration ("FDA") claim barred by the Supreme Court's ruling in *Buckman v. Plaintiff's Legal Comm*., 531 U.S. 341 (2001). Defendant argues that the "gravamen of the [Plaintiffs'] allegations is that Merck has been able to falsely represent the efficacy of the mumps component of its MMR vaccine by virtue of fraudulent submission of data during an FDA licensure process." (Dkt. No. 40 at 19.) Defendant contends that, because Supreme Court's decision in Buckman bars state fraud on the FDA claims, the Plaintiffs' state law claims must be dismissed. 531 at 348 (holding fraud on the FDA claims brought under state laws must be dismissed because such claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.A. § 301 et seq.). Alternatively, the Defendant claims that Plaintiffs' suit should be preempted because it would be impossible for Defendant to comply with both state laws and FDA labeling requirements. (Dkt. No. 40 at 20.)

In *Buckman*, the plaintiff sought to recover for injuries sustained from a medical device which gained FDA approval only after the defendant misrepresented its intended uses. 531 U.S. at 344. Plaintiff argued that, but for a fraud on the FDA, the medical device would not have been approved and Plaintiff's injuries would not have occurred. *Id*. The Court held that such a suit was preempted because state tort claims would upset the FDA's "delicate balance of statutory objectives." *Id*. at 348.

Buckman is unavailing. In its wake, courts considering arguments analogous to the one made here have found that, where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, a state tort claim is not preempted. *See In re Bayer Corp*. *Combination Aspirin Prods*. *Mktg*. *& Sales Practice*, 701 F. Supp.2d 356, 370 (E.D. N.Y. 2010) ("In order to avoid

preemption . . . a plaintiff's claim must thread the needle . . . showing that defendant has violated the FDCA, but that plaintiff's claims are not entirely premised on that violation . . . ."). Here, Plaintiffs allege that the deception was one part of a larger scheme to maintain an anticompetitive business regime. Therefore, while their claim alleges a violation of the FDCA, the claims are not entirely premised on that violation. (Dkt. 26 ¶ 27.) Additionally, in Buckman, the Court found that judgment in favor of the plaintiff "would exert extraneous pull" on the FDA's authority by limiting its ability to "police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350, 353. The case currently at bar does not implicate this concern. A ruling in favor of the Plaintiffs on these state claims would not have any effect on the method by which the FDA regulates the Defendant, or infringe on any FDA remedy to police fraud.

Moreover, decisions subsequent to *Buckman* have raised doubts about its precedential value outside the medical device context. In *Wyeth v*. *Levine*, the Supreme Court again considered whether the FDCA preempted a state tort suit. 555 U.S. 555, 563 (2009). The Court reasoned that, because no amendment to the FDCA ever permitted a federal remedy for consumers harmed by unsafe or ineffective drugs, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id*. at 574. Had Congress intended to preempt state lawsuits for medications, "it surely would have enacted an express preemption provision during the FDCA's 70-year history." *Id*.

Furthermore, *Wyeth* is instructive as it relates to the impossibility argument advanced by Defendant. Analogous to the instant case, defendant in Wyeth argued that it would be impossible to comply with the FDA regulatory scheme and avoid liability in tort. In response, the Court held

that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning…is difficult to accept." 555 U.S. at 570. This Court finds it difficult to accept that Defendant would be penalized for providing additional information on its warning label. Defendant has cited no instances of such an event. As a result, this Court rejects Defendant's argument that it would be impossible to comply both with state law and the FDCA at this stage.

In light of the foregoing, this Court finds that preemption does not bar Plaintiffs' state law claims.

iii. New York Deceptive Acts and Practices Claim

Plaintiff has adequately stated a claim under the New York Deceptive Acts and Practices Act ("NYDAPA"), N.Y. Gen. Bus. Law § 349(a) (McKinney 2014).

The NYDAPA prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349(a). The scope of this consumer protection statute "is intentionally broad, applying 'to virtually all economic activity.'" *Blue Cross and Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, 818 N.E.2d 1140, 1143 (N.Y. 2004) (quoting *Goshen v. Mut. Life Ins. Co. of N.Y.*, 774 N.E.2d 1190, 1195 (N.Y. 2002)). Courts have consistently found that anticompetitive behavior, when predicated on defendant's deceptive conduct, is actionable under NYDAPA. *See In re Automotive Refinishing Paint Antitrust Litig.*, 515 F. Supp.2d 544, 555 (E.D. Pa. 2007); *Leider v. Ralfe*, 387 F. Supp.2d 283, 295 (S.D.N.Y. 2005) ("[A]nticompetitive conduct that is not premised on consumer deception is not within the ambit of the statute."); *Cox v. Microsoft Corp.*,

778 N.Y.S.2d 147, 148 (App. Div. 2004) (plaintiffs state a claim where they allege defendant "engaged in purposeful, deceptive monopolistic business practices.").

To plead a claim under the NYDAPA, a plaintiff must demonstrate that: the defendant has (1) engaged in consumer oriented conduct that is (2) materially misleading and (3) the plaintiff has suffered injury as a result of the allegedly deceptive act or practice. *City of New York v. Smokes-Spirits.com, Inc.*, 911 N.E.2d 834, 838 (N.Y. 2009); *See also, Goshen*, 774 N.E.2d at 1195 (N.Y. 2002); *Stutman v. Chem. Bank*, 731 N.E.2d 608, 611 (N.Y. 2000).

To be "consumer oriented" within the meaning of the statute, a defendant's acts must have an impact broader than the particular plaintiffs, as opposed to a private contract dispute. *See New York v. Feldman*, 210 F. Supp.2d 294, 301 (S.D.N.Y. 2002) ("…[C]ourts have found sufficient allegations of injury to the public interest where plaintiffs plead repeated acts of deception directed at a broad group of individuals."); *Gaidon v. Guardian Life Ins. Co. of Am.*, 725 N.E.2d 598, 603 (N.Y. 1999) (finding sufficiently "consumer oriented" conduct where defendant engaged in an "extensive marketing scheme" that induced consumers at large to purchase a product); *Oswego Laborers Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 647 N.E.2d 741, 744 (N.Y. 1995) (deceptive practices "must have a broader impact on consumers at large."); *U.W. Marx, Inc. v. Bonded Concrete, Inc.*,776 N.Y.S.2d 617, 620 (App. Div. 2004) (dismissing a NYDAPA claim because it was a "complex private business transaction, not one based on a standard-form contract addressed to consumers generally."). "The critical question…is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or competitor." *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995).

Plaintiffs have alleged conduct that affects the public interest in New York. According to the Complaint, the Defendant falsely represented to consumers and the FDA that its product was substantially more effective than Defendant knew it to be. (Dkt. No. 26 ¶¶ 27, 83.) Defendant is alleged to have disseminated false advertising that helped maintain its monopoly and induced Plaintiff Klein in New York to purchase it at artificially high prices. (Dkt. 26 ¶¶ 11,13.) Such deception clearly impacts New York's interest in creating "an honest marketplace where trust, and not deception, prevails." *Goshen,* 774 N.E.2d at 1194-95 (internal citation omitted). The fact that the deception concerns a matter of public health—the state's ability to protect against Mumps outbreaks—further magnifies New York's interest. (Dkt. 26 ¶ 95.) As a result, the Complaint sufficiently states consumer oriented conduct.

Plaintiffs have sufficiently alleged a material deception within the meaning of the statute. "Whether a representation or an omission, the deceptive practice must be 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *Stutman*, 731 N.E.2d at 611-612 (quoting in part *Oswego*, 647 N.E.2d at 745).

According to the Amended Complaint, the FDA-approved insert accompanying the vaccine states that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons," (Dkt. No. 26 ¶ 85) even though Defendant knew that this was not true. (Dkt. No. 26 ¶ 62, 66, 83, 86.) Reasonable consumers—even reasonable physicians and reasonable pharmaceutical manufacturers—would be misled into believing that the vaccine was as effective as Defendant claimed.

Having previously considered whether Plaintiffs have suffered sufficient injury to support their claim, the Court need not expound much further on this point. Plaintiffs' allege economic

damage as a result of purchasing a questionable vaccine. (Dkt. No. 26 ¶¶ 167, 168.) Moreover, their Complaint alleges injury to the public interests in creating a fair market place (Dkt. No. 26 ¶¶ 111) and maintaining public health (Dkt. No. 26 ¶ 95.)

Defendant challenges Plaintiffs' Complaint on additional grounds. First, it argues that Plaintiffs have not alleged a deception within the state of New York. (Dkt. No. 43 at 23-24.) According to the Complaint, Plaintiff Klein is a medical doctor and resident of New York who purchased the mumps vaccine directly from the Defendant. (Dkt. No. 26 ¶ 13.) Drawing all reasonable inferences in favor of the Plaintiffs, the Court infers that Klein practices medicine in the state of New York and would therefore have been subject to Defendant's deception within that state.

Second, Defendant asserts that Plaintiffs failed to allege a fiduciary duty that would have obligated Defendant to disclose the existence of the efficacy information. (Dkt. No. 43 at 26.) There is simply no requirement in the NYDAPA that Plaintiffs plead a fiduciary duty. *See Smokes-Spirits.Com, Inc.*, 911 N.E.2d at 838; *Goshen*, 774 N.E.2d at 1195; *Stutman*, 731 N.E.2d at 611.

iv. The New Jersey Consumer Fraud Act Claim

The New Jersey Consumer Fraud Act ("CFA"), N.J. Stat. Ann. § 56:8-2 (West 2014), prohibits vendors of "merchandise" from engaging in "deception, fraud…or misrepresentation," or withholding any "material fact with intent that others rely upon such…omission" when purchasing the vendor's product.

At the outset, the Court notes that it must take care to balance its obligation to apply binding Third Circuit precedent, as well as the law of New Jersey as enunciated by its legislature

and Supreme Court. Accordingly, the Court must evaluate Plaintiffs' claim in accordance with the heightened pleading standard contained in Fed. R. Civ. P. 9(b). *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (a claim brought under the CFA "must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged.") (internal citation omitted). However, the Court also recognizes that New Jersey courts approach motions to dismiss in the CFA context "with hesitation." *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003), *certif. denied* 837 A.2d 1092 (N.J. 2003). Furthermore, consistent with long-held New Jersey Supreme Court precedent, this Court must construe this "remedial" statute "liberally" in its evaluation of the claim. *Real v. Radir Wheels, Inc.*, 969 A.2d 1069, 1075 (N.J. 2009) (quoting *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 929 A.2d 1076, 1079 n. 1 (N.J. 2007); *see also*, *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 364 (N.J. 1997) ("The history of the Act is one of constant expansion of consumer protection.").

As a threshold matter, this Court must decide whether the transaction between Plaintiff Suter and the Defendant falls within the realm of commercial activity governed by the CFA. *J&R Ice Cream Corp. v. Cal. Smoothie Licensing Corp.*, 31 F.3d 1259, 1273 (3d Cir. 1994) ("…[I]t is the character of the transaction rather than the identity of the purchaser which determines if the Consumer Fraud Act is applicable.").

Plaintiff Suter is a consumer of the Defendant's vaccine entitled to the CFA's protection. A consumer is "one who uses economic goods and so diminishes or destroys their utilities." *City Check Cashing, Inc. v. National State Bank*, 582 A.2d 809, 811 (N.J. Super. Ct. App. Div. 1990)

(citing *Hundred East Credit Corp. v. Eric Shuster*, 515 A.2d 246, 248 (N.J. Super. Ct. App. Div. 1986)), *certif. denied* 585 A.2d 391 (N.J. 1990). Where a commercial entity uses merchandise purchased for the conduct of its business, the commercial entity acts in a sufficiently consumer oriented manner for CFA purposes. *Coastal Grp., Inc. v. Dryvit Sys., Inc.*, 643 A.2d 649, 653 (N.J. Sup. Ct. App. Div. 1994) (citing *Hundred East Credit Corp.*, 515 A.2d at 248).

In light of the above, Plaintiff Suter is a consumer of the Defendant's vaccine. Plaintiff Suter uses the vaccine—an economic good—in the course of his medical practice and thereby destroys the vaccine's further utility. (Dkt. No. 26 ¶ 13.) Thus, he can accurately and fairly be considered to be a consumer of the vaccine. By contrast, he is not a reseller, or wholesaler who sells, but does not consume a particular product. Plaintiff Suter purchases the vaccine for his own private use which results in its total loss of utility. Thus, the Court finds that he is a consumer within the meaning of the statute.

Defendant argues that Plaintiff Suter acts as an intermediary between the Defendant and his patients and thus his transactions with Defendant are beyond the ambit of the statute. (Dkt. No. 40 at 27.) In making their argument, Defendant relies on *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 U.S. Dist. LEXIS 58900, at * 114-145 and *Cent. Reg'l Employees Benefit Fund v. Cephalon, Inc.*, No. 09-3418, 2009 U.S. Dist. LEXIS 93636. The Court is not persuaded. The factual scenario presented by the case at bar is simply not analogous to those in the cases cited by the Defendant. In both *Schering-Plough* and *Cent. Reg'l*, the court found that third-party-payors are not consumers because they do not purchase the medicine for their own consumption. Here, Plaintiff Suter purchases the vaccine to be consumed by his medical practice for the benefit of his medical practice. Thus, he is not a

middle-man or reseller in the sense described in *Schering-Plough* and *Cent. Reg'l*, and is therefore entitled to invoke the protection of the CFA.

Turning to the merits, a plaintiff properly before a court must demonstrate (1) unlawful conduct (i.e., deception, fraud or misrepresentation); (2) ascertainable loss; and, (3) a causal relationship between the unlawful conduct and the ascertainable loss. *Int'l Union of Operating Engineers*., 929 A.2d at 1086.

Plaintiffs have adequately alleged Defendant's unlawful conduct. For purposes of the CFA, there exist three general categories of unlawful practices, two of which are relevant here, with similar, but distinct pleading requirements: affirmative acts and knowing omissions. Plaintiff alleges both. (Dkt. 26 ¶ 163.) Defendant does not object to Plaintiffs' characterizations of its conduct both as affirmative acts and knowing omissions in either its Motion to Dismiss (Dkt. No. 40) or its Reply Brief (Dkt. No. 52). Therefore, the Court considers the issue waived for purposes of its decision here.

The parties dispute the ascertainable injury and causation elements. Defendant argues that Plaintiffs have failed to sufficiently allege an injury and, even if they have, Plaintiffs cannot demonstrate that their injury was caused by Defendant's misrepresentations. (Dkt. No. 27-28.) The Court disagrees with both assertions.

Plaintiffs have sufficiently stated an ascertainable loss. To prove this element, "a private plaintiff must produce evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss." *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792 (N.J. 2005). A plaintiff need not allege loss with scientific precision; rather, "an estimate of damages, calculated within a reasonable degree of certainty will suffice." *Id*. at 793. Here, Plaintiffs meet

that burden. They seek compensatory damages for the vaccine, and thus claim to have suffered a loss in the amount of the purchase price. (Dkt. No. 26 ¶ 169.) While they do not provide an exact dollar amount, the Plaintiffs have sufficiently provided the Court with a reasonable estimate of damages as required by *Thiedemann*. Moreover, the injury is pleaded with the particularity required by Fed. R. Civ. P. 9(b)—the purchase price being a sufficiently specific measurement of economic injury.

Plaintiffs have also adequately alleged causation. Defendant contends that Plaintiffs proffer a fraud-on-the-market theory of causation (Dkt. No. 27-28) which is expressly prohibited in the context of a CFA claim. *N.J. Citizen Action*, 842 A.2d at 178-179 (extending the prohibition on fraud-on-the-market theories in state securities litigation to CFA claims). Claims predicated on this type of theory allege that a price charged was higher than it should have been as a result of defendant's fraudulent marketing campaign. *Int'l Union of Operating Engr's* , 929 A.2d at 1088.

The Court is unmoved by Defendant's argument. Here, Plaintiffs allege that "as a direct and proximate result" of Defendant's "misrepresentations and omissions" they were deceived into purchasing Defendant's product. (Dkt. No. 26 ¶ 168.) They allege that they "would not have purchased or used Mumps Vaccine had they known the truth" about its efficacy. (Dkt. No. 26 ¶ 167.) Courts have found that this direct causation argument is sufficient to survive a motion to dismiss. *See e.g., In re Bayer Corp. Combination Aspirin Prods. Mktg. and Sales Practices Litig.*, 701 F.Supp.2d 356, 383 (E.D. N.Y. 2010) (denying a motion to dismiss for a fraud-on-the-market theory where plaintiff alleged that defendant's false promises themselves induced plaintiffs to purchase the product); *In re Ford Motor Co. E-350 Van Prods. Liability Litig.*, No.

03-4558, 2008 U.S. Dist. LEXIS 108085 (D.N.J. Nov. 18, 2009) (denying a motion to dismiss for fraud-on-the-market theory where plaintiff alleged defendant's deceptive representations themselves induced the plaintiffs to purchase defendant's product). Plaintiffs' theory parallels those found to be sufficient in those cases. Thus, the court finds that—at this stage in the litigation—the Plaintiffs have properly pleaded causation.

Given that this Court must construe the Complaint in the light most favorable to the plaintiff, construe the CFA liberally, and approach motions to dismiss "with hesitation," this Court finds that Plaintiffs have adequately pleaded a claim under the CFA.

v. Breach of Contract Claim

In Count III, Plaintiffs allege that Defendant breached contracts with the Plaintiffs by delivering vaccine with a lower-than-promised efficacy rate. As a result, Plaintiffs claim they were injured in the amount of the purchase price. This claim does not meet the pleading standards set forth in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

A plaintiff's obligation to plead his case extends beyond a formulaic recitation of the elements of a cause of action. *Twombly*, 550 U.S. 544 at 555 (internal citation omitted). Rather, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id*. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged misconduct." *Iqbal*, 556 U.S. at 678.

Here, Plaintiffs have not pled with sufficient detail. Aside from failing to invoke the contract law of any particular jurisdiction, the Complaint only alleges Defendant "entered into a

contract to provide Mumps Vaccine" and that Defendant's representation as to the efficacy of the vaccine "form[ed] the basis of the bargain." (Dkt. No. 26 ¶170, 172.) This is legally insufficient to survive 12(b)(6) scrutiny. Plaintiffs' proffer no information about contract formation, prices paid for the vaccine, dates of execution of the alleged contracts, quantities of vaccine purchased, actual efficacy rate of the vaccine purchased, or details of any other major term of the alleged contract. Given the scarcity of detail, the Court finds that there is insufficient factual content to advance the claims beyond the level of speculation, and as such, dismisses Count III without prejudice.

vi. Unjust Enrichment

In Count VI, Plaintiffs allege that Defendant was unjustly enriched. However, the Complaint fails to invoke the law of any particular jurisdiction. Accordingly, the Court finds that Plaintiffs have failed to meet the applicable pleading standards.

The degree of specificity required in a class action alleging unjust enrichment is not a legal question of first impression within this district. In two prior cases, courts in this district have dismissed Complaints where the plaintiffs failed to invoke the law of any particular jurisdiction. *See In re Flonase Antitrust Litig*., 610 F.Supp.2d 409, 419 (E.D. Pa. 2009) (granting leave to amend the complaint where plaintiff failed to specify the state laws they invoke); *In re Wellbutrin XL Antitrust Litig*., 260 F.R.D. 143, 167 (E.D. Pa. 2009) (dismissing an unjust enrichment claim for failing to "reference any basis in law on which a claim…might proceed.").

Consistent with those holdings, this Court dismisses Plaintiffs' Count VI without prejudice.

vii. Conclusion

For the reasons above, the Court will grant Defendant's Motion to Dismiss for lack of standing all state claims arising under the laws of jurisdictions in which the named Plaintiffs do not reside. The court rejects Defendant's argument that Plaintiffs' surviving state claims are preempted by Federal law, and finds that Plaintiffs have adequately stated claims under the consumer protection statutes of New York and New Jersey. However, the Court finds that Plaintiffs have failed to state claims for breach of contract and unjust enrichment. Thus, the Court dismisses Count II, except for claims brought under the NYDAPA and the NJCFA; and, dismisses Count III, Count IV, Count V, and Count VI in their entireties.

An appropriate order follows.

Exhibit C

MOTREF,STANDARD

United States District Court
Eastern District of Pennsylvania (Philadelphia)
CIVIL DOCKET FOR CASE #: 2:10-cv-04374-CDJ

UNITED STATES OF AMERICA et al. v. MERCK & CO.
Assigned to: HONORABLE C. DARNELL JONES, II
Referred to: MAGISTRATE JUDGE LYNNE A. SITARSKI (Settlement)
all others Case: 2:12-cv-03857-CDJ
related Cases: 2:12-cv-03555-CDJ
2:14-cv-06447-CDJ
Cause: 31:3729 False Claims Act

Date Filed: 08/27/2010
Jury Demand: Both
Nature of Suit: 890 Other Statutes: Other Statutory Actions
Jurisdiction: U.S. Government Plaintiff

Plaintiff

UNITED STATES OF AMERICA *EX REL.*

represented by **DANIEL J. VITELLI**
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-350-2700
Email: dvitelli@constantinecannon.com
TERMINATED: 03/11/2015
LEAD ATTORNEY

GERALD B. SULLIVAN
ASSISTANT U.S. ATTORNEY - US ATTY'S OFFICE
615 CHESTNUT ST., STE. 1250
PHILADELPHIA, PA 19106-4476
215-861-8786
Fax: 215-861-8349
Email: gerald.sullivan@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL M. SWEET
U.S. ATTORNEY'S OFFICE
615 CHESTNUT STREET
SUITE 1250
PHILADELPHIA, PA 19106
215-861-8581
Fax: 215-861-8618
Email: joel.sweet@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

MARGARET L. HUTCHINSON
U.S. ATTORNEY'S OFFICE
615 CHESTNUT STREET
SUITE 1250
PHILADELPHIA, PA 19106
215-861-8282
Fax: 215-861-8618
Email: margaret.hutchinson@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL C. MEREDITH
MEREDITH & ASSOCIATES
1521 LOCUST STREET
7TH FLOOR
PHILADELPHIA, PA 19102
215-564-5182
Email: jmeredith@mcgslaw.com
ATTORNEY TO BE NOTICED

JOHN A. MACORETTA
SPECTOR ROSEMAN & KODROFF, P.C.
1818 MARKET STREET
SUITE 2500
PHILADELPHIA, PA 19103
215-496-0300
Fax: 215-496-6611
Email: jmacoretta@srkattorneys.com
ATTORNEY TO BE NOTICED

Plaintiff

STEPHEN A. KRAHLING represented by **DANIEL B. ALLANOFF**
MEREDITH COHEN GREENFOGEL & SKINICK PC
1521 LOCUST ST., 8TH FL
PHILADELPHIA, PA 19102
215-564-5182
TERMINATED: 02/18/2016
LEAD ATTORNEY

DANIEL J. VITELLI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

GORDON SCHNELL
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL

NEW YORK, NY 10017
212-350-2700
Email: gschnell@constantinecannon.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

HAMSA MAHENDRANATHAN
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-350-2700
Email:
hmahendranathan@constantinecannon.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

HOLLIS L. SALZMAN
ROBINS KAPLAN LLP
399 Park Avenue
Suite 3600
NEW YORK, NY 10022
212-980-7405
Email: hsalzman@robinskaplan.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JASON ENZLER
CONSTANTINE CANNON LLP
1001 PENNSYLVANIA AVE NW STE
1300N
WASHINGTON, DC 20004-2579
202-204-3500
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JEFFREY F. KELLER
KELLER GROVER LLP
1965 MARKET ST
SAN FRANCISCO, CA 94103
415-543-1305
Email: jfkeller@kellergrover.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL C. MEREDITH
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOHN A. MACORETTA
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KATHLEEN R. SCANLAN
KELLER GROVER LLP
1965 MARKET ST
SAN FRANCISCO, CA 94103
415-543-1305
Email: kscanlan@kellergrover.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KELLIE LERNER
ROBINS KAPLAN LLP
399 Park Avenue
Suite 3600
NEW YORK, NY 10022
212-980-7400
Email: klerner@robinskaplan.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

MARLENE KOURY
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-350-2769
Email: mkoury@constantinecannon.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ROBERT L. BEGLEITER
CONSTANTINE CANNON LLP
335 MADISON AVE 9TH FL
NEW YORK, NY 10017
212-612-0686
Email: rbegleiter@constantinecannon.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

JOAN A. WLOCHOWSKI represented by **DANIEL B. ALLANOFF**
(See above for address)
TERMINATED: 02/18/2016
LEAD ATTORNEY

DANIEL J. VITELLI

(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

GORDON SCHNELL
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

HAMSA MAHENDRANATHAN
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

HOLLIS L. SALZMAN
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JASON ENZLER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JEFFREY F. KELLER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JEFFREY L. KODROFF
SPECTOR ROSEMAN & KODROFF PC
1818 MARKET STREET
SUITE 2500
PHILADELPHIA, PA 19103
215-496-0300
Fax: 215-496-6611
Email: jkodroff@srkattorneys.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOEL C. MEREDITH
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KATHLEEN R. SCANLAN
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KELLIE LERNER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

MARLENE KOURY
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ROBERT L. BEGLEITER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

JOHN A. MACORETTA
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

MERCK & CO. represented by **DINO S. SANGIAMO**
VENABLE LLP
750 E PRATT ST STE 900
BALTIMORE, MD 21202
410-244-7679
Email: dssangiamo@venable.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KATHLEEN SULLIVAN HARDWAY
VENABLE LLP
750 E. PRATT STREET
SUITE 900
BALTIMORE, MD 21202
410-528-2842
Email: khardway@venable.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

SALLY W. BRYAN
VENABLE LLP
750 EAST PRATT ST
BALTIMORE, MD 21202
410-244-7704
Email: srbryan@venable.com
LEAD ATTORNEY

ATTORNEY TO BE NOTICED

ERIC W. SITARCHUK
MORGAN LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921
215-963-5840
Fax: 215-963-5001
Email: esitarchuk@morganlewis.com
ATTORNEY TO BE NOTICED

LISA DYKSTRA
MORGAN LEWIS & BOCKIUS
1701 MARKET STREET
PHILADELPHIA, PA 19103
215-963-5699
Fax: 215-963-5001
Email: ldykstra@morganlewis.com
ATTORNEY TO BE NOTICED

MARGARET E. RODGERS SCHMIDT
MORGAN LEWIS & BOCKIUS LLP
1701 MARKET ST.
PHILADELPHIA, PA 19103
215-963-5163
Email:
mrodgersschmidt@morganlewis.com
ATTORNEY TO BE NOTICED

R. BRENDAN FEE
MORGAN LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103
215-963-5136
Email: bfee@morganlewis.com
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
04/27/2010	20	COMPLAINT against MERCK & CO. (Filing fee $ 350 receipt number 028702.), filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.(ti,) (Entered: 06/21/2012)
04/27/2010		DEMAND for Trial by Jury by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/21/2012)
08/27/2010	2	ENTRY of Appearance by JOEL M. SWEET on behalf of UNITED STATES OF AMERICA with Certificate of Service(ti,) (Entered: 06/20/2012)
09/22/2010	3	

		ENTRY of Appearance by GERALD B. SULLIVAN on behalf of UNITED STATES OF AMERICA with Certificate of Service(ti,) (Entered: 06/20/2012)
10/22/2010	5	ORDER THAT THE MOTION IS GRANTED. THE COMPLAINT, DOCKET ENTRIES, AND ALL RELATED FILINGS, INCLUDING THE UNITED STATES' MOTION SHALL REMAIN UNDER SEAL AN ADDITIONAL SIX MONTHS, UNTIL AND INCLUDING 4/27/2011 OR FURTHER ORDER OF THIS COURT. THE US' PERIOD IN WHICH TO ELECT TO INTERVENE IS EXTENDED SIX MONTHS, UNTIL 4/27/2011. THE CLERK SHALL DELIVER A COPY OF THIS ORDER ONLY TO COUNSEL FOR THE US AND RELATORS. SIGNED BY HONORABLE C. DARNELL JONES, II ON 10/22/10. 6/20/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/20/2012)
05/06/2011	7	ORDER THAT THE MOTION IS GRANTED. THE US' PERIOD TO INTERVENE IS EXTENDED SIX MONTHS UNTIL AND INCLUDING 10/27/2011. THE COMPLAINT, DOCKET ENTRIES, AND ALL RELATED FILINGS INCLUDING THE US' MOTION AND SUPPORTING MEMORANDUM OF LAW, SHALL OTHERWISE REMAIN UNDER SEAL. THE CLERK SHALL DELIVER A COPY OF THIS ORDER ONLY TO COUNSEL FOR THE US AND COUNSEL FOR THE RELATORS. SIGNED BY HONORABLE C. DARNELL JONES, II ON 5/4/11. 6/20/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/20/2012)
10/27/2011	9	ORDER THA THE MOTION FOR EXTENSION OF SEAL IS GRANTED. THE PERIOD IN WHICH TO ELECT WHETHER TO INTERVENE IS EXTENDED UNTIL 4/27/2012. THE COMPLAINT AND ALL RELATED FILINGS SHALL REMAIN UNDER SEAL UNTIL 4/27/2012. SIGNED BY HONORABLE C. DARNELL JONES, II ON 10/27/11. 6/20/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/20/2012)
01/30/2012	10	ENTRY of Appearance by JOEL C. MEREDITH on behalf of STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI (ti,) (Entered: 06/20/2012)
04/26/2012	11	UNCONTESTED MOTION FOR EXTENSION OF THE SEAL ON QUI TAM ACTION AND RELATED FILINGS, Certificate of Service filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.(ti,) (Entered: 06/21/2012)
04/27/2012	13	ORDER THAT THE MOTION IS GRANTED. THE COMPLAINT, DOCKET ENTRIES, AND ALL RELATED FILINGS, INCLUDING THE RELATORS' MOTION, SHALL REMAIN UNDER SEAL UNTIL AND INCLUDING 5/29/2012, OR UNTIL FURTHER ORDER OF THE COURT, ETC. SIGNED BY HONORABLE C. DARNELL JONES, II ON 4/27/12. 6/20/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/20/2012)
04/27/2012	12	AMENDED COMPLAINT with Jury Trial Demand against MERCK & CO., filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.(ti,) (Entered: 06/21/2012)
04/27/2012	14	NOTICE of Election to Decline Intervention with Certificate of Service by UNITED STATES OF AMERICA (ti,) (Entered: 06/21/2012)

05/01/2012	15	ORDER THAT THE COMPLAINT, THIS ORDER, AND THE US' NOTICE OF ELECTION TO DECLINE SHALL REMAIN UNDER SEAL INDEFINITELY AND SHALL NOT BE MADE PUBLIC OR SERVED UPON THE DEFENDANT OR THE RELATORS; PARTIES SHALL SERVE ALL PLEADINGS AND MOTIONS FILED IN THIS ACTION AFTER THE DATE OF THIS ORDER; PARTIES SHALL SERVE ALL NOTICES OF APPEAL UPON THE US; ALL ORDERS OF THIS COURT SHALL BE SENT TO THE US; AND SHOULD THE RELATORS OR THE DEFENDANT PROPOSE THAT THIS ACTION BE DISMISSED, SETTLED, OR OTHERWISE DISCONTINUED THE COURT WILL SOLICIT THE WRITTEN CONSENT OF THE US BEFORE FULING OR GRANTING ITS APPROVAL. SIGNED BY HONORABLE C. DARNELL JONES, II ON 4/30/12. 6/20/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/20/2012)
05/24/2012	16	MOTION TO KEEP UNDER SEAL TWO PARAGRAPHS OF THE ORIGINAL-FILED COMPLAINT, Memorandum in Support, Certificate of Service filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.(ti,) (Entered: 06/21/2012)
05/30/2012	17	ORDER THAT RELATORS' MOTION IS GRANTED; IT IS FURTHER ORDERED THAT PARAGRAPHS 52 AND 53 OF RELATORS COMPLAINT FOR VIOLATIONS REMAIN UNDER SEAL UNTIL FURTHER ORDER OF THIS COURT; IT IS FURTHER ORDERED THAT WITHIN 3 BUSINESS DAYS OF THE UNSEALING OF THE RECORD IN THIS ACTION, RELATORS WILL SERVE UPON DEFENDANT A COPY OF THE UNREDACTED COMPLAINT FOR VIOLATIONS; AND IT IS FURTHER ORDERED THAT THE COPY OF THE RELATORS' COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT PARAGRAPHS 52 AND 53 REDACTED, WILL BE AVAILABLE TO THE PUBLIC UPON THE UNSEALING OF THE RECORD IN THIS ACTION. SIGNED BY HONORABLE C. DARNELL JONES, II ON 5/30/12. 6/21/12 ENTERED AND COPIES MAILED.(ti,) (Entered: 06/21/2012)
06/06/2012	18	Revised Proposed Order Relating to MOTION to Keep Under Seal Two Paragraphs of the Original-Filed Complaint and Related Filings filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Main Document 18 replaced on 6/21/2012) (ti,). (Entered: 06/21/2012)
06/08/2012	19	ORDER THAT RELATORS' MOTION IS GRANTED; IT IS FURTHER ORDERED THAT PARAGRAPHS 52 AND 53 OF RELATORS' COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, DATED 8/27/2010, SHALL REMAIN UNDER SEAL UNTIL FURTHER ORDER OF THIS COURT; IT IS FURTHER ORDERED THAT THE REDACTED COMPLAINT, AMENDED COMPLAINT AND THE RECORD IN THIS ACTION BE UNSEALED UPON THE SIGNING OF THIS ORDER, AND THAT THE CLERK SHALL ISSUE SUMMONS IN THIS CASE. IT IS FURTHER ORDERED THAT UPON UNSEALING THE RECORD IN THIS ACTION, AND THE ISSUANCE OF THE SUMMONS, RELATORS WILL SERVE UPON THE DEFENDANT A COPY OF THE UNREDACTED COMPLAINT; AND IT IS FURTHER ORDERED THAT

		THE COPY OF RELATORS' COMPLAINT PARAGRAPHS 52 AND 53 REDACTED, ATTACHED TO THIS ORDER AS EXHIBIT A, WILL BE AVAILABLE TO THE PUBLIC UPON THE UNSEALING OF THE RECORD IN THIS ACTION. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/7/12. 6/21/12 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 06/21/2012)
06/18/2012	21	JOINT MOTION TO UNSEAL THE RECORD EXCEPT FOR DOCKET NUMBERS 1, 4, 6 AND 8, Memorandum in Support filed by STEPHEN A. KRAHLING, UNITED STATES OF AMERICA, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/21/2012)
06/19/2012	22	ORDER THAT THE JOINT MOTION IS GRANTED AND EXCEPT FOR THE DOCKET NUMBERS 1, 4, 6, AND 8, THE RECORD IN THIS ACTION IS HEREBY UNSEALED; IT IS FURTHER ORDERED THAT DOCKET NO. 1, WHICH IS THE ORIGINAL, UNREDACTED COMPLAINT, DATED 8/27/2010, SHALL REMAIN UNDER SEAL UNTIL FURTHER ORDER OF THE COURT; IT IS FURTHER ORDERED THAT DOCKET NOS. 4, 6, AND 8, WHICH ARE MOTIONS BY THE US, SHALL REMAIN UNDER SEAL INDEFINITELY. IT IS FURTHER ORDERED THAT THE PARTIES SHALL SERVE ALL PLEADING AND MOTIONS FILED IN THIS ACTION, INCLUDING SUPPORTING MEMORANDA, UPON THE US; THE PARTIES SHALL SERVE ALL NOTICES OF APPEAL UPON THE US; ALL ORDERS OF THIS COURT SHALL BE SENT TO THE US; AND SHOULD THE RELATORS OR THE DEFENDANT PROPOSE THIS ACTION BE DISMISSED, SETTLED, OR ORTHERWISE DISCONTINUED, THE COURT WILL SOLICIT THE WRITTEN CONSENT OF THE US BEFORE RULING OR GRANTING ITS APPROVAL. IT IS FURTHER ORDERED THAT UPON THE SIGNING OF THIS ORDER, THE CLERK SHALL ISSUE SUMMONS IN THIS CASE; AND IT IS FURTHER ORDERED THAT UPON UNSEALING THE RECORD IN THIS ACTION, AND THE ISSUANCE OF THE SUMMONS, RELATORS WILL SERVE UPON DEFENDANT A COPY OF THE UNREDACTED COMPLAINT AND THE AMENDED COMPLAINT. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/19/12. 6/21/12 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 06/21/2012)
06/19/2012		Summons Issued as to MERCK & CO. One Original Forwarded To: Counsel - Relators on 6/21/12 (ti,) (Entered: 06/21/2012)
06/21/2012	23	NOTICE of Appearance by ERIC W. SITARCHUK on behalf of MERCK & CO. with Notice of Appearance of Eric W. Sitarchuk and Lisa C. Dykstra with Certificate of Service(SITARCHUK, ERIC) (Entered: 06/21/2012)
06/22/2012	24	NOTICE of Appearance by LISA DYKSTRA on behalf of MERCK & CO. with Certificate of Service(DYKSTRA, LISA) (Entered: 06/22/2012)
06/28/2012	25	APPLICATION OF ROBERT L. BEGLEITER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number

		065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/28/2012	26	APPLICATION OF JASON ENZLER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/28/2012	27	APPLICATION OF JEFFREY F. KELLER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/28/2012	28	APPLICATION OF MARLENE KOURY, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/28/2012	29	APPLICATION OF KATHLEEN R. SCANLAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/28/2012	30	APPLICATION OF GORDON SCHNELL, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065358) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 06/28/2012)
06/29/2012	31	Disclosure Statement Form pursuant to FRCP 7.1 with Certificate of Service by MERCK & CO..(SITARCHUK, ERIC) (Entered: 06/29/2012)
06/29/2012	32	ORDER THAT THE APPLICATION OF ROBERT L. BEGLEITER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 07/02/2012)
06/29/2012	33	ORDER THAT THE APPLICATION OF JASON ENZLER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/02/2012)
06/29/2012	34	ORDER THAT THE APPLICATION OF JEFFREY F. KELLER, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/02/2012)

06/29/2012	35	ORDER THAT THE APPLICATION OF MARLENE KOURY, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/02/2012)
06/29/2012	36	ORDER THAT THE APPLICATION OF KATHLEEN R. SCANLAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/02/2012)
06/29/2012	37	ORDER THAT THE APPLICATION OF GORDON SCHNELL, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/29/12. 7/2/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/02/2012)
07/06/2012	38	APPLICATION OF SALLY W. BRYAN, ESQUIRE TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065765) by MERCK & CO. (ti,) (Entered: 07/06/2012)
07/06/2012	39	APPLICATION OF DINO S. SANGIAMO, ESQUIRE TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), Statement, Certificate of Service (Filing fee $40 receipt number 065765) by MERCK & CO. (ti,) (Entered: 07/06/2012)
07/09/2012	40	ORDER THAT THE APPLICATION OF SALLY W. BRYAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 7/9/12. 7/10/12 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 07/10/2012)
07/09/2012	41	ORDER THAT THE APPLICATION OF DINO S. SANGIAMO, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 7/9/12. 7/10/12 ENTERED AND COPIES MAILED, E-MAILED. (ti,) (Entered: 07/10/2012)
07/11/2012	42	AFFIDAVIT of Service by C & E Legal Courier Service, Inc. re: served Amended Complaint and Summons upon Merck & Co.c/o CT Corporation by Personal on June 27, 2012 (NARINE, KRISHNA) (Entered: 07/11/2012)
07/11/2012	43	AFFIDAVIT of Service by C & E Legal Courier Service, Inc. re: served Amended Complaint and Summons upon Merck & Co. c/o Lisa Dykstra by Personal on June 27, 2012 (NARINE, KRISHNA) (Entered: 07/11/2012)
07/27/2012	44	ORDER THAT THE DEFENDANT SHALL FILE IS RESPONSIVE PLEADING ON OR BEFORE 8/31/2012, ETC. SIGNED BY HONORABLE C. DARNELL JONES, II ON 7/27/12. 7/27/12 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 07/27/2012)

08/31/2012	45	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by MERCK & CO..Memorandum, Certificate of Service. (Attachments: # 1 Memorandum in Support, # 2 Exhibit A, # 3 Proposed Order, # 4 Certificate of Service)(SITARCHUK, ERIC) (Entered: 08/31/2012)
09/27/2012	46	ORDER THAT RELATORS SHALL FILE THEIR OPPOSITION BRIEF TO MERCK'S MOTION TO DISMISS ON OR BEFORE 10/9/2012; DEFENDANT SHALL FILE LEAVE FOR A REPLY BRIEF, ATTACHING THE REPLY BRIEF THERETO, ON OR BEFORE 10/30/2012. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/26/12. 9/27/12 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/27/2012)
10/09/2012	47	RESPONSE in Opposition re 45 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (SCHNELL, GORDON) (Entered: 10/09/2012)
10/09/2012	48	AFFIDAVIT in Opposition re 45 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM *Declaration of Marlene Koury In Support of Relators Opposition to Motion to Dismiss* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Text of Proposed Order, # 7 Certificate of Service)(SCHNELL, GORDON) (Entered: 10/09/2012)
10/31/2012	49	MOTION for Leave to File *a Reply Brief* filed by MERCK & CO..Memorandum, Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Proposed Reply Brief, # 3 Exhibit B)(SITARCHUK, ERIC) (Entered: 10/31/2012)
11/05/2012	50	ORDER THAT UPON CONSIDERATION OF DEFENDANT'S MOTION FOR LEAVE TO FILE A REPLY BRIEF, AND ANY RESPONSES THERETO, IT IS HEREBY ORDERED THAT THE DEFENDANT'S MOTION IS GRANTED. THE CLERK OF COURT IS DIRECTED TO FILE THE REPLY BRIEF IN THE ABOVE CAPTIONED ACTION FORTHWITH. SIGNED BY HONORABLE C. DARNELL JONES, II ON 11/5/12. 11/5/12 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 11/05/2012)
11/05/2012	51	REPLY BRIEF in Support 45 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by MERCK & CO. (ti,) (Entered: 11/07/2012)
01/17/2013	52	NOTICE by STEPHEN A. KRAHLING, UNITED STATES OF AMERICA, JOAN A. WLOCHOWSKI of Change of Firm Affiliation.(MEREDITH, JOEL) (INCORRECT PDF; ATTY HAS RE-FILED AT PAPER #53) Modified on 1/22/2013 (md). (Entered: 01/17/2013)
01/18/2013	53	NOTICE by STEPHEN A. KRAHLING, UNITED STATES OF AMERICA, JOAN A. WLOCHOWSKI *of Change of Firm Affiliation* (MEREDITH, JOEL) (Entered: 01/18/2013)
05/20/2013	54	Statement *of Interest Addressing Merck's Motion to Dismiss* by UNITED STATES OF AMERICA. (Attachments: # 1 Exhibit A)(SULLIVAN, GERALD) (Entered: 05/20/2013)

05/20/2013	55	NOTICE of Withdrawal of Appearance by JOEL M. SWEET on behalf of UNITED STATES OF AMERICA(SWEET, JOEL) (Entered: 05/20/2013)
06/14/2013	56	ORDER THAT ORAL ARGUMENTS SHALL BE HELD ON THE PENDING MOTION TO DISMISS ON 7/31/2013, AT 11:00 AM. SIGNED BY HONORABLE C. DARNELL JONES, II ON 6/14/13. 6/14/13 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 06/14/2013)
08/09/2013	57	Transcript of Proceedings held on 7/31/13, before Judge C. Darnell Jones, II. Court Reporter/Transcriber Katie Furphy. (ti,) (Entered: 08/12/2013)
03/19/2014	58	NOTICE of Appearance by JOEL M. SWEET on behalf of UNITED STATES OF AMERICA with Certificate of Service(SWEET, JOEL) (Entered: 03/19/2014)
09/04/2014	59	MEMORANDUM AND/OR OPINION SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/4/14. 9/5/14 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/05/2014)
09/04/2014	60	ORDER THAT UPON CONSIDERATION OF DEFENDANTS' MOTION TO DISMISS IN CIVIL ACTION NO. 12-3555 (DKT NO. 40), IT IS HEREBY ORDERED THAT SAID MOTION IS GRANTED IN PART AND DENIED IN PART. UPON CONSIDERATION OF DEFENDANTS' MOTION TO DISMISS IN CIVIL ACTION NO. 10-4374 (DKT NO. 45), IT IS HEREBY ORDERED THAT SAID MOTION IS DENIED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/4/14. 9/5/14 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/05/2014)
09/05/2014	61	AMENDED MEMORANDUM AND/OR OPINION SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/5/14. 9/5/14 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/05/2014)
09/19/2014	62	ANSWER to 12 Amended Complaint by MERCK & CO.. (Attachments: # 1 Certificate of Service)(DYKSTRA, LISA) (Entered: 09/19/2014)
10/14/2014	63	Joint report of RULE 26(f) meeting by MERCK & CO.. (DYKSTRA, LISA) Modified on 10/15/2014 (afm,). (Entered: 10/14/2014)
10/15/2014	64	ORDER THAT A FED. R. CIV. P. 16 CONFERENCE SHALL BE HELD BY TELEPHONE ON 11/13/2014, AT 1:30 PM, ETC. SIGNED BY HONORABLE C. DARNELL JONES, II ON 10/15/14. 10/16/14 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 10/16/2014)
11/06/2014	65	Application of Daniel J. Vitelli, Esq. to practice in this Court pursuant to LRCP 83.5.2(b) (Pro Hac Vice) on behalf of STEPHEN A. KRAHLING, UNITED STATES OF AMERICA, JOAN A. WLOCHOWSKI, Statement, Certificate of Service ($40 Filing Fee Pd. - Receipt #110876). (fdc) (Entered: 11/06/2014)
11/13/2014	66	ORDER THAT THE APPLICATION OF DANIEL J. VITELLI, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C.

		DARNELL JONES, II ON 11/13/14. 11/13/14 ENTERED AND COPIES E-MAILED.(ti,) Modified on 11/13/2014 (ti,). (Entered: 11/13/2014)
11/14/2014	67	ORDER THAT ANY AND ALL FUTURE DISCOVERY MOTIONS IN BOTH ABOVE-CAPTIONED MATTERS ARE REFERRED TO THE HONORABLE LYNNE A. SITARSKI, UNITED STATES MAGISTRATE JUDGE, FOR DISPOSITION PURSUANT TO 28 U.S.C. 636(b)(1)(A). FACT DISCOVERY SHALL BE COMPLETED BY 9/29/2015. ALL EXPERT DISCOVERY SHALL BE COMPLETED BY 3/31/2016. ALL DISPOSITIVE MOTIONS SHALL BE FILED AND SERVED ON 4/29/2016. PLAINTIFF SHALL FILE AND SERVE ITS MOTION FOR CLASS CERTIFICATION BY 7/8/2016. SIGNED BY HONORABLE C. DARNELL JONES, II ON 11/13/14. 11/17/14 ENTERED AND COPIES E-MAILED.(ti,) Modified on 11/17/2014 (ti,). (Entered: 11/17/2014)
12/09/2014	68	NOTICE to join letter motion to enter protective order and compel by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI (VITELLI, DANIEL) Modified on 12/10/2014 (afm,). (Entered: 12/09/2014)
01/26/2015	69	PROTECTIVE ORDER WITH COURT APPROVAL RE: CERTAIN STATEMENTS; ETC.. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 1/26/15. 1/26/15 ENTERED AND E-MAILED.(jl,) (Additional attachment(s) added on 1/26/2015: # 1 AGREEMENT) (jl,). (Entered: 01/26/2015)
01/30/2015	70	ORDER REGARDING PRODUCTION OF DOCUMENTS AND INFORMATION SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 1/30/15. 2/2/15 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 02/02/2015)
02/25/2015	71	JOINT STIPULATION AND ORDER THAT FACT DISCOVERY SHALL BE COMPLETED BY 3/1/2016. ALL EXPERT DISCOVERY SHALL BE COMPLETED BY 10/31/2016. ALL DISPOSTIVE MOTIONS SHALL BE FILED AND SERVED ON 12/9/2016. PLAINTIFFS SHALL FILE AND SERVE THEIR MOTION FOR CLASS CERTIFICATION BY 2/7/2017, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 2/24/15. 2/25/15 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 02/25/2015)
03/11/2015	72	NOTICE of Withdrawal of Appearance by DANIEL J. VITELLI on behalf of All Plaintiffs (VITELLI, DANIEL) (Entered: 03/11/2015)
03/20/2015	73	NOTICE of Appearance by R. BRENDAN FEE on behalf of MERCK & CO. with Certificate of Service(FEE, R.) (Entered: 03/20/2015)
04/13/2015	74	APPLICATION OF HAMSA MAHENDRANATHAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b), *Statement and Certificate of Service* (Filing fee $40 receipt number 119280) by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (ti,) (Entered: 04/14/2015)
04/14/2015	75	ORDER THAT THE APPLICATION OF HAMSA MAHENDRANATHAN, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL

		RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 4/14/15. 4/15/15 ENTERED AND ECF APPLICATION & COPIES MAILED, E-MAILED.(ti,) (Entered: 04/15/2015)
06/01/2015	76	Letter to Judge Sitarski re: To compel Merck to respond to Interrogatories filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.. (Attachments: # 1 Text of Proposed Order)(SCHNELL, GORDON) Modified on 6/2/2015 (afm,). (Entered: 06/01/2015)
06/15/2015	77	RESPONSE in Opposition re 76 MOTION to Compel filed by MERCK & CO.. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Text of Proposed Order)(DYKSTRA, LISA) (Entered: 06/15/2015)
06/22/2015	78	LETTER REPLY to Response to Motion re 76 MOTION to Compel filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D)(SCHNELL, GORDON) Modified on 6/23/2015 (afm,). (Entered: 06/22/2015)
07/15/2015	79	ORDER THAT AN IN-PERSON MEET AND CONFER WILL BE HELD ON 7/27/2015, AT 1:00 PM, IN COURTROOM 3-E, U.S. COURTHOUSE, 601 MARKET STREET, PHILADELPHIA, PA 19106. IF APPROPRIATE, THE COURT SHALL CONDUCT AN ORAL ARGUMENT IMMEDIATELY THEREAFTER ON RELATORS' LETTER MOTION TO COMPEL, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 7/15/15. 7/16/15 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 07/16/2015)
07/16/2015	80	ORDER THAT AN IN-PERSON MEET AND CONFER WILL BE HELD ON 7/22/2015, AT 1:30 PM, IN COURTROOM 3-E, U.S. COURTHOUSE, 601 MARKET STREET, PHILADELPHIA, PA 19106. IF APPROPRIATE, THE COURT SHALL CONDUCT AN ORAL ARGUMENT IMMEDIATELY THEREAFTER ON RELATORS' LETTER MOTION TO COMPEL, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 7/15/15. 7/16/15 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 07/17/2015)
07/17/2015	81	Minute Entry for proceedings held before MAGISTRATE JUDGE LYNNE A. SITARSKI Telephonic Pretrial Conference held on 7/16/15. (ti,) (Entered: 07/17/2015)
07/31/2015	82	Minute Entry for proceedings held before MAGISTRATE JUDGE LYNNE A. SITARSKI Oral Argument held on 7/22/15 (ti,) (Entered: 07/31/2015)
07/31/2015	83	ORDER THAT RELATORS MOTION IS GRANTED TO THE EXTENT RELATORS SEEK TO COMPEL MERCK'S ANSWER TO INTERROGATORY NUMBER 1. RELATORS MOTION IS DENIED TO THE EXTENT RELATOR SEEKS TO COMPEL MERCK'S ANSWERS TO RFA 1,2,12,14,27,28,38,40,55,57,71 AND 72 AND INTERROGATORY NUMBER 1, ETC.. SIGNED BY MAGISTRATE JUDGE LYNNE A.

		SITARSKI ON 7/31/15. 7/31/15 ENTERED AND COPIES MAILED, E-MAILED.(rf,) (Entered: 07/31/2015)
08/13/2015	84	Objections by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI re 83 Order, Terminate Deadlines and Hearings,, *Relators Written Statement of Objections to Judge Sitarskis July 31, 2015 Order*. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(SCHNELL, GORDON) (Entered: 08/13/2015)
08/14/2015	85	Transcript of Hearing held on 7/22/15, before Judge Lynne A. Sitarski. Court Reporter/Transcriber ESR/DIANA DOMAN TRANSCRIBING, LLC. (ti,) Modified on 8/18/2015 (afm,). (Entered: 08/17/2015)
08/27/2015	86	Response to Relators' Written Statement of Objections to Judge Sitarski's July 31, 2015 Order by MERCK & CO., CERTIFICAE OF SERVICE. (Attachments: # 1 Exhibit 1, # 2 Text of Proposed Order, # 3 Certificate of Service)(DYKSTRA, LISA) Modified on 8/28/2015 (afm,). (Entered: 08/27/2015)
09/16/2015	87	ORDER THAT SAID OBJECTIONS ARE OVERRULED. JUDGE SITARSKI'S 7/31/15 ORDER IS AFFIRMED. RELATORS MOTION IS DENIED; ETC.. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/16/15. 9/17/15 ENTERED AND E-MAILED.(jl,) (Entered: 09/17/2015)
10/21/2015	88	MOTION to Seal Document *[Motion for Protective Order]* filed by JOAN A. WLOCHOWSKI.. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(SCHNELL, GORDON) (Entered: 10/21/2015)
10/22/2015	89	LETTER MOTION FOR PROTECTIVE ORDER filed by JOAN A. WLOCHOWSKI. (FILED UNDER SEAL)(ti,) (Entered: 10/22/2015)
11/03/2015	90	LETTER RESPONSE to Motion re 88 MOTION to Seal Document *[Motion for Protective Order]* filed by MERCK & CO.. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(DYKSTRA, LISA) Modified on 11/4/2015 (afm,). (Entered: 11/03/2015)
11/05/2015	91	ORDER THAT UPON CONSIDERATION OF RELATOR JOAN WLOCHOWSKI'S LETTER REQUEST FOR PERMISSION TO FILE THEIR MOTION FOR A PROTECTIVE ORDER UNDER SEAL 88 , IT IS HEREBY ORDERED THAT THE REQUEST IS GRANTED AND RELATOR WLOCHOWSKI'S MOTION FOR PROTECTIVE ORDER SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 11/4/15. 11/5/15 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 11/05/2015)
11/05/2015	92	ORDER THAT UPON CONSIDERATION OF DEFENDANT'S LETTER REQUEST FOR PERMISSION TO FILE ITS RESPONSE TO THE MOTION FOR A PROTECTIVE ORDER UNDER SEAL 90 , IT IS HEREBY ORDERED THAT THE REQUEST IS GRANTED AND DEFENDANT'S RESPONSE TO MOTION FOR PROTECTIVE ORDER SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 11/4/15. 11/5/15 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 11/05/2015)

11/10/2015	93	LETTER REQUEST to Seal Document *[Reply re: Motion for Protective Order]* filed by JOAN A. WLOCHOWSKI, CERTIFICATE OF SERVICE.. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service) (SCHNELL, GORDON) Modified on 11/12/2015 (afm,). (Entered: 11/10/2015)
11/12/2015	94	REPLY *to MERCK's Opposition to MOTION (Doc. No. 89) for Protective Order* filed by JOAN A. WLOCHOWSKI. (FILED UNDER SEAL) (ti,) (Entered: 11/12/2015)
11/12/2015	95	ORDER THAT UPON CONSIDERATION OF RELATOR JOAN WLOCHOWSKI'S LETTER REQUEST 93 , IT IS HEREBY ORDERED THAT THE REQUEST IS GRANTED AND RELATOR WLOCHOWKSI'S REPLY TO DEFENDANT'S RESPONSE TO MOTION FOR PROTECTIVE ORDER SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 11/12/15. 11/13/15 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 11/13/2015)
01/11/2016	96	JOINT STIPULATION AND ORDER THAT FACT DISCOVERY SHALL BE COMPLETED BY 3/1/2017. ALL EXPERT DISCOVERY SHALL BE COMPLETED BY 10/31/2017. ALL DISPOSITIVE MOTIONS SHALL BE FILED AND SERVED ON 12/20/2017. PLAINTIFFS SHALL FILE AND SERVE THEIR MOTION FOR CLASS CERTIFICATION BY 3/1/2018. DEFENDANT SHALL FILE AND SERVE ITS OPPOSITION TO CLASS CERTIFICATION BY 4/5/2018, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 1/8/16. 1/12/16 ENTERED AND COPIES E-MAILED.(ti,) Modified on 1/12/2016 (ti,). (Entered: 01/12/2016)
02/05/2016	97	MEMORANDUM AND/OR OPINION SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 2/5/16. 2/8/16 ENTERED AND COPIES MAILED. (ti,) Modified on 2/19/2016 (ti,). (ti,). Modified on 2/19/2016 (afm,).(UNSEALED PER ORDER 101) (Entered: 02/08/2016)
02/05/2016	98	ORDER THAT RELATOR'S MOTION IS DENIED, AS OUTLINED. OUT OF UTMOST CAUTION, AND BECAUSE RELATOR'S MOTION AND THE PARTIES' RESPONSES ARE ALL FILED UNDER SEAL, THE COURT FILES ITS MEMORANDUM UNDER SEAL. AFTER REVIEWING THE COURT'S MEMORANDUM, THE PARTIES ARE ORDERED TO SHOW CAUSE BY 2/16/2016 WHY THE COURT'S MEMORANDUM SHOULD REMAIN UNDER SEAL. SHOULD THE PARTIES FAIL TO SHOW CAUSE, THE COURT WILL UNSEAL THE MEMORANDUM ON 2/17/2016. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 2/5/16. 2/8/16 ENTERED AND COPIES E-MAILED.(ti,) Modified on 2/8/2016 (ti,). (Entered: 02/08/2016)
02/09/2016	99	Statement *(Letter to The Honorable Lynne A. Sitarski)* by MERCK & CO.. (DYKSTRA, LISA) (Entered: 02/09/2016)
02/10/2016	100	letter Response to Court's February 5, 2016 Order (ECF No. 98)] by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (SCHNELL, GORDON) Modified on 2/10/2016 (afm,). (Entered: 02/10/2016)

02/18/2016		Copy of Order dated 2/5/16 and envelope returned from the U.S. Postal Service addressed to DANIEL B. ALLANOFF for the following reason: Deceased. (ti,) (Entered: 02/18/2016)
02/18/2016	101	ORDER THAT UPON CONSIDERATION OF THE PARTIES' LETTERS (ECF NOS. 99, 100), INFORMING THE COURT THAT THEY DO NOT OPPOSE THE COURT'S UNSEALING OF THE COURT'S 2/5/2016 MEMORANDUM 97 , IT IS HEREBY ORDERED THAT THE COURT'S MEMORANDUM IS UNSEALED. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 2/18/16. 2/19/16 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 02/19/2016)
03/03/2016		Copy of Order dated 2/5/16 and envelope returned from the U.S. Postal Service addressed to JASON ENZLER for the following reason: Forward Expired; Re-mailed to 1001 Pennsylvania Avenue, NW, Suite 1300N, Washington, DC 20004-2579. (ti,) (Entered: 03/03/2016)
12/02/2016	102	STIPULATION AND ORDER REGARDING DEPOSITION PROTOCOL SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 12/2/16. 12/5/16 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 12/05/2016)
12/06/2016	103	NOTICE of Appearance by DANIEL J. VITELLI on behalf of STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI with Certificate of Service (VITELLI, DANIEL) (Entered: 12/06/2016)
02/08/2017	104	APPLICATION for Admission Pro Hac Vice of Kathleen S. Hardway by MERCK & CO.. (Filing fee $ 40 receipt number 0313-11857811.). (DYKSTRA, LISA) (Entered: 02/08/2017)
02/21/2017	105	MOTION Leave to Depose Relators for Two Seven-Hour Days *(Letter Motion to Judge Sitarski)* filed by MERCK & CO... (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Text of Proposed Order)(DYKSTRA, LISA) (Entered: 02/21/2017)
02/24/2017	106	NOTICE by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI *Change of Firm Affiliation* (MEREDITH, JOEL) (Entered: 02/24/2017)
02/28/2017	107	Joint STIPULATION and (Proposed) Order to amend the amended scheduling order by STEPHEN A. KRAHLING. (FORWARD TO JUDGE FOR APPROVAL) (lvj,) (Entered: 03/01/2017)
03/01/2017	108	STIPULATION AND ORDER TO AMEND THE AMENDED SCHEDULING ORDER. THE FACT DISCOVERY COMPLETION DEADLINE SHALL BE EXTENDED TO 6/1/2017, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 3/1/17. 3/1/17 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 03/01/2017)
03/07/2017	109	Letter RESPONSE in Opposition re 105 MOTION Leave to Depose Relators for Two Seven-Hour Days *(Letter Motion to Judge Sitarski)* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (KOURY, MARLENE) Modified on 3/8/2017 (afm,). (Entered: 03/07/2017)

03/14/2017	110	REPLY to Response to Motion re 105 MOTION Leave to Depose Relators for Two Seven-Hour Days *(Letter Motion to Judge Sitarski)* filed by MERCK & CO.. (Attachments: # 1 Exhibit 9)(DYKSTRA, LISA) (Entered: 03/14/2017)
03/15/2017	111	ORDER THAT UPON CONSIDERATION OF DEFENDANT'S LETTER MOTION FOR LEAVE TO DEPOSE RELATORS FOR TWO SEVEN-HOUR DAYS 105 , IT IS HEREBY ORDERED THAT DEFENDANT'S MOTION IS GRANTED. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 3/15/17.3/15/17 ENTERED AND COPIES MAILED, E-MAILED.(ti,) (Entered: 03/15/2017)
03/17/2017	112	ORDER: THAT THE REQUEST IS GRANTED. GLAXOSMITHKLINE SHALL RESPOND TO THE MOION TO COMPEL ON OR BEFORE MARCH 31, 2017. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 3/17/2017. 3/17/2017 ENTERED AND COPIES E-MAILED AND FAXED. (sme,) (Entered: 03/17/2017)
03/20/2017	113	Minute Entry for Telephonic Discovery Dispute held on 3/20/17, before Magistrate Judge SITARSKI. (ti,) (Entered: 03/20/2017)
03/27/2017	114	ORDER THAT KATHLEEN S HARDWAY, ESQUIRE, TO PRACTICE IN THIS COURT PURSUANT TO LOCAL RULE OF CIVIL PROCEDURE 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 3/27/17. 3/27/17 ENTERED AND ECF APPLICATION & COPIES MAILED, E-MAILED.(ti,) (Entered: 03/27/2017)
04/05/2017	115	ORDER THAT UPON CONSIDERATION OF PLAINTIFF'S LETTER MOTION TO COMPEL NON-PARTY GLAXOSMITHKLINE, LLC TO PRODUCE DOCUMENTS 114 , AND THE NON-PARTY GLAXOSMITHKLINE'S RESPONSE THERETO 117 , IT IS HEREBY ORDERED THAT PLAINTIFF'S MOTION IS DENIED WITHOUT PREJUDICE. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 4/5/17. 4/5/17 ENTERED AND COPIES E-MAILED.(ti,) Modified on 4/6/2017 (lisad,). (Entered: 04/05/2017)
04/18/2017	116	LETTER MOTION to Seal Document *[Motion to Compel Discovery Relating to Potency and Stability of Mumps Vaccines]* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(VITELLI, DANIEL) Modified on 4/19/2017 (lisad,). (Entered: 04/18/2017)
04/19/2017	117	LETTER MOTION TO COMPEL filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (FILED UNDER SEAL)(ti,)(Additional attachment(s) added on 4/19/2017: # 1 Sealed Document, # 2 Sealed Document, # 3 Sealed Document, # 4 Sealed Document, # 5 Sealed Document, # 6 Sealed Document, # 7 Sealed Document, # 8 Sealed Document) (lisad,). Modified on 4/19/2017 (lisad,). (Entered: 04/19/2017)
04/24/2017	118	NOTICE of Appearance by MARGARET E. RODGERS SCHMIDT on behalf of MERCK & CO. with Certificate of Service(RODGERS SCHMIDT, MARGARET) (Entered: 04/24/2017)
04/26/2017	119	

		LETTER to the Honorable Lynne A. Sitarski by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI *re: April 18, 2017 letter* (VITELLI, DANIEL) Modified on 4/27/2017 (lisad,). (Entered: 04/26/2017)
04/27/2017	120	ORDER THAT UPON CONSIDERATION OF RELATORS' LETTER REQUEST FOR PERMISSION TO FILE UNDER SEAL THEIR MOTION TO COMPEL AND EXHIBITS 116 , IT IS HEREBY ORDERED THAT THE REQUEST IS GRANTED AND RELATORS' MOTION TO COMPEL AND EXHIBITS SHALL BE FILED UNERE SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 4/27/17.4/27/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 04/27/2017)
04/27/2017	121	STIPULATION AND ORDER THAT THE PARTIES HEREBY STIPULATE AND AGREE, AND THE COURT HEREBY ORDERS, THAT DEFENDANT IS TO FILE ITS OPPOSITION TO THE MOTION BY 5/9/2017, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 4/27/17. 4/27/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 04/27/2017)
05/05/2017	122	LETTER to the Honorable Lynne A. Sitarski by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI *re: April 18, 2017 letter* (VITELLI, DANIEL) Modified on 5/8/2017 (lisad,). (Entered: 05/05/2017)
05/08/2017	123	*Letter to the Court re: Relators' and Plaintiffs' May 5, 2017 Letter* by MERCK & CO. re 122 Notice (Other) (DYKSTRA, LISA) Modified on 5/9/2017 (lisad,). (Entered: 05/08/2017)
05/08/2017	124	Minute Entry for Telephonic Discovery Dispute held on 5/8/17, before MAGISTRATE JUDGE LYNNE A. SITARSKI. (lisad,) Modified on 5/10/2017 (lisad,). (Main Document 124 replaced on 5/10/2017) (lisad,). (Entered: 05/10/2017)
05/09/2017	125	LETTER to the Honorable Lynne A. Sitarski re request to file under seal *Opposition and Exhibits to Relators' and Plaintiffs' Motion to Compel Discovery relating to Potency and Stability of Mumps Vaccine (Dkt. No. 117)* filed by MERCK & CO..Certificate of Service. (Attachments: # 1 Certificate of Service, # 2 Text of Proposed Order)(DYKSTRA, LISA) Modified on 5/10/2017 (lisad,). (Entered: 05/09/2017)
05/10/2017	126	ORDER THAT THE REQUEST IS GRANTED AND MERCK'S OPPOSITION AND EXHIBITS TO RELATORS' AND PLAINTIFF'S MOTION TO COMPEL SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 5/10/17.5/10/17 ENTERED AND COPIES E-MAILED.(ti,) Modified on 5/10/2017 (ti,). (Entered: 05/10/2017)
05/10/2017	127	OPPOSITION AND EXHIBITS TO RELATORS' AND PLAINTIFFS' MOTION TO COMPEL DISCOVERY RELATING TO POTENCY AND STABILITY OF MUMPS VACCINES (DOC. NO. 117) filed by MERCK & CO. (FILED UNDER SEAL) (aeg) Modified on 5/11/2017 (lisad,). (Entered: 05/11/2017)
05/16/2017	128	

		LETTER to the Honorable Lynne A. Sitarski re request for permission to file reply and exhibits under seal filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.Reply Brief and Exhibits 1 - 6. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(VITELLI, DANIEL) Modified on 5/17/2017 (lisad,). (Entered: 05/16/2017)
05/16/2017	129	LETTER REPLY in Support of 117 MOTION *to Compel together with Exhibits* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (FILED UNDER SEAL) (ti,) (lisad,). Modified on 5/17/2017 (lisad,). (Entered: 05/17/2017)
05/17/2017	130	ORDER THAT UPON CONSIDERATION OF RELATORS' LETTER REQUEST FOR PERMISSION TO FILE UNDER SEAL THEIR REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL AND EXHIBITS 128 , IT IS HEREBY ORDERED THAT THE REQUEST IS GRANTED AND PLAINTIFFS' REPLY AND ITS EXHIBITS SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 5/17/17.5/18/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 05/18/2017)
05/25/2017	131	STIPULATION AND ORDER THAT ALL EXPERT DISCOVERY SHALL BE COMPLETED BY 4/30/2018. ALL DISPOSITIVE MOTIONS SHALL BE FILED AND SERVED ON 6/19/2018. PLAINTIFFS SHALL FILE AND SERVE THEIR MOTION FOR CLASS CERTIFICATION BY 9/11/2018, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 5/25/17. 5/26/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 05/26/2017)
05/25/2017	132	STIPULATION AND ORDER THAT THE PARTIES AGREE, THAT MERCK'S TIME TO RESPOND TO RELATORS' THRID SET OF REQUESTS FOR ADMISSION AND PLAINTIFFS' FIRST SET OF INTERROGATORIES IS EXTENDED TO 6/21/2017, AND RELATORS' TIME TO RESPOND TO MERCK'S SECOND SET OF INTERROGATORIES IS EXTENDED TO 6/22/2017. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 5/25/17. 5/26/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 05/26/2017)
07/24/2017	133	ORDER THAT UPON CONSIDERATION OF RELATORS' MOTION TO COMPEL 117 , IT IS HEREBY ORDERED THAT THE RELATORS' MOTION IS DENIED. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 7/24/17.7/24/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 07/24/2017)
08/07/2017	134	MOTION to Seal Document *[Plaintiffs Objections to July 24, 2017 Order]* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service) (VITELLI, DANIEL) (Entered: 08/07/2017)
08/07/2017	135	Plaintiffs' Objections to Magistrate's Court's 133 Order (FILED UNDER SEAL) (ti,) (Additional attachment(s) added on 8/8/2017: # 1 Sealed Document, # 2 Sealed Document, # 3 Sealed Document, # 4 Sealed Document, # 5 Sealed Document, # 6 Sealed Document, # 7 Sealed Document, # 8 Sealed

		8/29/2017 (ti,). (Additional attachment(s) added on 8/30/2017: # 1 sealed documents, # 2 sealed documents, # 3 sealed documents, # 4 sealed documents, # 5 sealed documents, # 6 sealed documents, # 7 sealed documents, # 8 sealed documents, # 9 sealed documents) (tjd,). (Entered: 08/29/2017)
08/30/2017	143	MOTION to Seal *Merck's Motion for Summary Judgment Against Relator Krahling* filed by MERCK & CO..Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(DYKSTRA, LISA) (Entered: 08/30/2017)
08/30/2017	144	ORDER THAT RELATORS' & PRIVTE ANTITRUST PLFFS' MOTION REQUESTING PERMISSION TO FILE UNDER SEAL PLFFS' MOTION FOR LEAVE TO REPLY TO MERCK'S RESPONSE TO PLFFS' OBJECTIONS TO MAGISTRATE JUDGE SITARSKI'S 7/24/2017 DISCOVERY ORDER IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 8/30/17.8/30/17 ENTERED AND COPIES E-MAILED.(kw,) (Entered: 08/30/2017)
08/30/2017	145	MOTION for Summary Judgment filed by MERCK & CO. EXHIBITS, MEMORANDUM, CERTIFICATE OF SERVICE. (FILED UNDER SEAL) (jl,) Modified on 8/31/2017 (lisad,). (Additional attachment(s) added on 8/31/2017: # 1 Sealed Document, # 2 Sealed Document, # 3 Sealed Document, # 4 Sealed Document, # 5 Sealed Document, # 6 Sealed Document, # 7 Sealed Document, # 8 Sealed Document, # 9 Sealed Document, # 10 Sealed Document, # 11 Sealed Document, # 12 Sealed Document, # 13 Sealed Document, # 14 Sealed Document, # 15 Sealed Document, # 16 Sealed Document, # 17 Sealed Document, # 18 Sealed Document, # 19 Sealed Document, # 20 Sealed Document, # 21 Sealed Document, # 22 Sealed Document, # 23 Sealed Document, # 24 Sealed Document, # 25 Sealed Document, # 26 Sealed Document, # 27 Sealed Document, # 28 Sealed Document, # 29 Sealed Document, # 30 Sealed Document, # 31 Sealed Document, # 32 Sealed Document, # 33 Sealed Document, # 34 Sealed Document, # 35 Sealed Document, # 36 Sealed Document, # 37 Sealed Document, # 38 Sealed Document, # 39 Sealed Document, # 40 Sealed Document, # 41 Sealed Document, # 42 Sealed Document, # 43 Sealed Document, # 44 Sealed Document, # 45 Sealed Document, # 46 Sealed Document, # 47 Sealed Document, # 48 Sealed Document, # 49 Sealed Document) (lisad,). Modified on 8/31/2017 (lisad,). (Entered: 08/31/2017)
08/31/2017	146	ORDER THAT THE 143 MOTION TO SEAL MERCK'S MOTION FOR SUMMARY JUDGMENT IS GRANTED.. SIGNED BY HONORABLE C. DARNELL JONES, II ON 8/31/2017.9/1/2017 ENTERED AND COPIES E-MAILED.(kp,) (Entered: 09/01/2017)
09/01/2017	147	MOTION to Seal Document *[Motion to Stay Merck's Motion for Summary Judgment]* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(SCHNELL, GORDON) (Entered: 09/01/2017)
09/01/2017	148	

		MOTION TO TOLL THE TIMING OF ANY RESPONSE re 145 MOTION for Summary Judgment filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(SCHNELL, GORDON) (Entered: 09/01/2017)
09/01/2017	149	RELATORS' MOTION TO STAY MERCK'S MOTION FOR SUMNMARY JUDGMENT AGAINST RELATOR KRAHLING, MEMORANDUM, CERTIFICATE OF SERVICE. (FILED UNDER SEAL)(mbh,) (Additional attachment(s) added on 9/5/2017: # 1 Memorandum, # 2 Exhibit A, # 3 Certificate of Service, # 4 Text of Proposed Order) (fb). Modified on 9/5/2017 (fb). (Entered: 09/05/2017)
09/07/2017	150	ORDER THAT UPON CONSIDERATION OF THE JULY 24, 2017 ORDER, ISSUED BY THE HONORABLE LYNNE A. SITARSKI, U.S. MAGISTRATE JUDGE 133 , PLAINTIFF'S OBJECTIONS THERETO 135 , DEFENDANT'S RESPONSE 138 , AND PLAINTIFFS' REPLY (ECF NO. 142-4), IT IS HEREBY ORDERED THAT PLAINTIFFS' OBJECTIONS ARE OVERRULED; AND JUDGE SITARSKI'S ORDER IS AFFIRMED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/7/17. 9/7/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/07/2017)
09/08/2017	151	JOINT STIPULATION to Amend the Scheduling Order by STEPHEN A. KRAHLING, UNITED STATES OF AMERICA, JOAN A. WLOCHOWSKI. (MACORETTA, JOHN) (FILED IN ERROR BY ATTY) Modified on 9/11/2017 (md). (Entered: 09/08/2017)
09/08/2017	152	ORDER THAT UPON CONSIDERATION OF RELATORS' AND PRIVATE ANTITRUST PLAINTIFFS' MOTION TO LEAVE TO FIEL A REPLY TO MERCK'S RESPOSNE TO PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE SITARSKI'S 7/24/2017 DISCOVERY ORDER, IT IS HEREBY ORDERED THAT THE MOTION IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/8/17.9/11/17 ENTERED AND COPIES E-MAILED.(ti,) (Main Document 152 replaced on 9/11/2017) (ti,). (Entered: 09/11/2017)
09/08/2017	153	ORDER THAT UPON CONSIDERATION OF RELATORS' MOTION REQUESTING PERMISSION TO FILE UNDER SEAL RELATORS' MOTION TO STAY MERCK'S MOTION FOR SUMMARY JUDGMENT AGAINST RELATOR KRAHLING, IT IS HEREBY ORDERED THAT THE MOTION IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/8/17.9/11/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/11/2017)
09/11/2017	154	STIPULATION AND ORDER TO AMEND THE SCHEDULING ORDER, DISCOVERY DUE BY 7/19/2018., DISPOSITIVE MOTIONS DUE BY 9/14/2018. ETC.. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 9/11/2017. 9/11/2017 ENTERED AND COPIES E-MAILED. (sg,) (Entered: 09/11/2017)
09/14/2017	155	MOTION to Seal *Merck's Omnibus Opposition to Relators' Motions to Stay and Toll the Time to Respond to Merck's Motion for Summary Judgment*

		Against Relator Krahling filed by MERCK & CO..Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service) (DYKSTRA, LISA) (Entered: 09/14/2017)
09/14/2017	156	MERCK'S OMNIBUS OPPOSITION TO RELATORS' MOTIONS TO STAY AND TOLL THE TIME TO RESPOND TO MERCK'S MOTION FOR SUMMARY JUDGMENT AGAINST RELATOR KRAHLING filed by MERCK & CO..CERTIFICATE OF SERVICE. (FILED UNDER SEAL)(kp,) (Additional attachment(s) added on 9/15/2017: # 1 Sealed Document, # 2 Sealed Document, # 3 Sealed Document, # 4 Sealed Document) (md,). (Entered: 09/15/2017)
09/15/2017	157	ORDER THAT MOTION TO SEAL IS GRANTED. SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/15/17. 9/15/17 ENTERED AND COPIES EMAILED.(rf,) (Entered: 09/15/2017)
09/19/2017	158	ORDER THAT UPON CONSIDERATION OF RELATORS' MOTION TO TOLL THE TIMING OF ANY RESPONSE RE DEFENDANT'S MOTION FOR SUMMARY JUDGMENT 148 , RELATORS' MOTION TO STAY MERCK'S MOTION FOR SUMMARY JUDGMENT 149 , AND DEFENDANT'S OMNIBUS OPPOSITION TO RELATORS' MOTIONS TO STAY AND TOLL THE TIME TO RESPOND 156 , AS WELL AS PLAINTIFFS' MOTION FOR LEAVE TO FILE A SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND DEFENDANT'S OPPOSITION THERETO, IT IS HEREBY ORDERED THAT THOSE THREE MOTIONS ARE REFERRED TO THE HONORABLE LYNNE A. SITARSKI, U.S. MAGISTRATE JUDGE, FOR DISPOSITION PURSUANT TO 28 U.S.C. 636(b)(1)(A). SIGNED BY HONORABLE C. DARNELL JONES, II ON 9/18/17. 9/20/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/20/2017)
09/19/2017		MOTIONS REFERRED: (ti,) (Entered: 09/20/2017)
09/20/2017	159	MOTION to Seal Document *[REPLY IN SUPPORT OF RELATORS MOTIONS TO STAY AND TOLL THE TIMING OF ANY RESPONSE TO MERCK'S SUMMARY JUDGMENT MOTION AGAINST RELATOR KRAHLING]* filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(SCHNELL, GORDON) (Entered: 09/20/2017)
09/20/2017	160	REPLY in Support of 148 and 149 *Motions to Stay and Toll the Timing of any Response to Merck's Summary Judgment Motion against Relator Krahling,* together with Certificate of Service filed by STEPHEN A. KRAHLING, JOAN A. WLOCHOWSKI. (FILED UNDER SEAL) (ti,) (Additional attachment(s) added on 9/21/2017: # 1 Sealed Document, # 2 Sealed Document, # 3 Sealed Document) (lisad,). (Entered: 09/21/2017)
09/22/2017	161	ORDER THAT UPON CONSIDERATION OF RELATORS' MOTION REQUESTING PERMISSION TO FILE UNDER SEAL RELATORS' REPLY IN SUPPORT OF THEIR MOTIONS TO STAY AND TOLL THE TIMING OF ANY RESPONSE TO MERCK'S MOTION FOR SUMMARY

		JUDGMENT AGAINST RELATOR KRAHLING 159 , IT IS HEREBY ORDERED THAT THE MOTION IS GRANTED, AND THE RELATORS' REPLY AND ITS EXHIBITS SHALL BE FILED UNDER SEAL. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 9/22/17.9/22/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 09/22/2017)
10/27/2017	162	ORDER THAT RELATOR'S MOTION TO STAY MERCK'S MOTION FOR SUMMARY JUDGMENT (DOC. NO. 149) IS GRANTED; AND THAT RELATOR'S MOTION TO TOLL THE TIMING OF ANY RESPONSE TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (DOC. NO. 148) IS DENIED AS MOOT. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 10/27/2017. 10/27/2017 ENTERED AND COPIES E-MAILED. (aeg) (Entered: 10/27/2017)
12/22/2017	163	JOINT STIPULATION AND ORDER THAT ALL EXPERT DISCOVERY SHALL BE COMPLETED BY 9/7/2018. ALL DISPOSITIVE MOTIONS SHALL BE FILED AND SERVED ON 10/29/2018. PLAINTIFFS SHALL FILE AND SERVE THEIR MOTION FOR CLASS CERTIFICATION BY 2/15/2019, ETC. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 12/22/17. 12/26/17 ENTERED AND COPIES MAILED, E-MAILED.(ti,) Modified on 12/26/2017 (ti,). (Entered: 12/26/2017)
04/06/2018	164	JOINT STIPULATION AND ORDER REGARDING EXPERT DISCOVERY. SIGNED BY MAGISTRATE JUDGE LYNNE A. SITARSKI ON 4/6/18. 4/6/18 ENTERED AND COPIES MAILED AND EMAILED TO COUNSEL.(jaa,) Modified on 4/6/2018 (jaa,). (Entered: 04/06/2018)
04/24/2018	165	Letter to the Honorable C. Darnell Jones II and the Honorable Lynne A. Sitarski re timing of depositions filed by MERCK & CO... (Attachments: # 1 Exhibit A)(DYKSTRA, LISA) Modified on 4/25/2018 (lisad,). (Entered: 04/24/2018)