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VIA EMAIL TO INDIVIDUAL DELEGATES

New York State Bar Association
House of Delegates
1 Elk Street
Albany, New York 12207

Re: *Informed Consent Action Network Concerns Regarding COVID-19 vaccines*

Dear NYSBA Delegate:

Our client, Informed Consent Action Network ("**ICAN**"), has asked us to bring to your attention critical and noteworthy issues regarding the current COVID-19 vaccines in development, prior to your November meeting. ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions.

ICAN has received numerous notes and complaints from its supporters in New York regarding the NYSBA's COVID-19 report, dated May 13, 2020, which recommended that "[w]hen the efficacy of a COVID-19 vaccine has been confirmed, enact legislation requiring vaccination of each person unless the person's physician deems vaccination for his or her patient to be clinically inappropriate."[1] It is ICAN's understanding that this recommendation will be discussed at the next House of Delegates meeting.

On behalf of its constituents in New York, and in order to provide a more complete understanding of the ramifications of supporting such a recommendation, ICAN herein brings the following issues to your attention, each equally deserving of your attention: (i) serious concerns with the COVID-19 vaccine clinical trials with regard to both safety and efficacy; (ii) conflicts of interest that exist in the "independent" data safety & monitoring boards overseeing the trials for these potential vaccines; (iii) financial conflicts of interest within the National Institutes of Health with regard to these potential vaccines; (iv) the immunity to liability bestowed upon the vaccine manufacturers by the federal government for any injury caused by these potential vaccines; (v) the

[1] https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf (last visited August 11, 2020).

superior natural immunity to SARS-CoV-2 that policymakers have failed to take into account; (vi) the unique issues related to children and SARS-CoV-2; and (vii) the critical need for vaccine exemptions in New York State.

ICAN respectfully requests that you devote the time and attention needed to understand these concerns before voting on whether to recommend a mandate and thereby quashing the right of New Yorkers' to make medical decisions with informed consent.

I. The Issues with the Clinical Trials of the COVID-19 Vaccines

The current Phase III clinical trials for each of the four frontrunner COVID-19 vaccines are inadequate. These trials should comport with the best scientific practices. However, evidence to date shows that these trials do not comport with best practices.

To that end, ICAN, through counsel, filed formal petitions with the Food and Drug Administration ("**FDA**") regarding the Phase III clinical trials of four potential COVID-19 vaccines setting forth certain deficiencies in these trials (collectively, the "**Petitions**"):

1. mRNA-1273 sponsored by Moderna TX, Inc. in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID)[2] (the "**Moderna/NIAID Vaccine**")[3];

2. BNT162b sponsored by BioNTech SE in collaboration with Pfizer (the "**BioNTech/Pfizer Vaccine**"); [4]

3. ChAdOx1 nCoV-19 sponsored by the University of Oxford in collaboration with AstraZeneca (the "**Oxford/AstraZeneca Vaccine**")[5]; and

4. Ad26.COV2.S sponsored by Johnson & Johnson (the "**Johnson & Johnson Vaccine**")[6] (collectively, the "**COVID-19 Vaccines**").

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[2] The National Institute of Allergy and Infectious Disease ("NIAID").

[3] Moderna/NIAID Vaccine: Docket No. FDA-2020-P-1769; Citizen Petition and all Amended Petitions available at: https://beta.regulations.gov/document/FDA-2020-P-1769-0001. NCT04470427 available at https://www/clinicaltrials.gov/ct2/showNCT04470427 (last visited October 26, 2020).

[4] BioNTech/Pfizer Vaccine: Docket No. FDA-2020-P-1770; Citizen Petition and all Amended Petitions available at: https://beta.regulations.gov/document/FDA-2020-P-1770-0001. NCT04368728 available at https://www/clinicaltrials.gov/ct2/show/NCT04368728 (last visited October 26, 2020).

[5] Oxford/AstraZeneca Vaccine: Docket No. FDA-2020-P-1768; Citizen Petition and all Amended Petitions available at: https://beta.regulations.gov/document/FDA-2020-P-1768-0001. NCT04400838 available at https://www/clinicaltrials.gov/ct2/show/NCT04400838 (last visited October 26, 2020).

[6] Johnson & Johnson Vaccine: Docket No. FDA-2020-P-2096; Citizen Petition available at: https://www.regulations.gov/docket?D=FDA-2020-P-2096; NCT04505722 available at https://www.clinicaltrials.gov/ct2/show/NCT04505722 (last visited October 26, 2020).

Each Petition demands that the FDA require an adequate study design for each of these trials. Because of the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the FDA, and potentially recommended as a mandate by the NYSBA, ICAN has requested that the FDA enact specific requirements for each vaccine.

A. The COVID-19 Vaccines' Clinical Trials

All four COVID-19 Vaccine Petitions request that the study design for the Phase III trials of each vaccine be amended to provide that:

1. Any and All Adverse Events and Reactions[7] Should be Documented for the Entire Duration of the Trial

Adverse events are a concern with any vaccine and especially now, in the current atmosphere, when vaccine hesitancy is reported to be at an all-time high and the vaccine platforms being tested are novel. Nevertheless, in many instances, the study designs for the leading COVID-19 vaccines allow the clinical researchers to subjectively determine whether adverse events ("**AEs**") suffered by study participants are related to the vaccine or not. To increase assurance that potential adverse events from the COVID-19 Vaccines are captured, all AEs and reactions should be documented for each subject post-vaccination, whether or not they are considered vaccine-related by the investigator or sponsor, for the full duration of the clinical trial.[8]

Furthermore, the study designs for the COVID-19 Vaccines provide that data regarding AEs will only be captured for a short period of time. For example, AEs will be recorded for *only 28 days* (Oxford/AstraZeneca Vaccine, Moderna/NIAID, and Johnson & Johnson vaccine for only a small subset of participants) or 1 month (BioNTech/Pfizer) after vaccination. Some of those same study designs call for SAEs, and sometimes MAAEs to continue to be captured for longer (Oxford/AstraZeneca Vaccine and BioNTech/Pfizer).[9]

Part of the problem with these plans concerns the definitions of AEs vs. SAEs or MAAEs. There are many autoimmune, neurological, and chronic health disorders which have a major impact on patient's quality of life, yet are categorized by the FDA as "adverse reactions" and not

[7] Including, but not limited to, systemic adverse reactions, adverse events, non-serious adverse event, serious adverse events, medically-attended adverse events, new onset medical conditions, and any other health issue of any degree or type arising or exacerbated post-vaccination, whether suspected, unexpected, expected or otherwise, and whether or not considered related to the vaccine.

[8] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32 (last visited Aug. 21, 2020) (defining "Adverse event" as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related"); https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event (last visited Aug. 21, 2020). All AEs and reactions should include but should not limited to: all systemic adverse reactions; adverse events; non-serious adverse events; serious adverse events ("**SAEs**"); medically-attended adverse events ("**MAAEs**"); new onset medical conditions; and any other health issue of any degree or type arising or exacerbated post-vaccination, whether suspected, unexpected, expected or otherwise, and whether or not considered related to the vaccine.

[9] As the Principal Deputy Commissioner of the FDA, along with her colleagues at the FDA, wrote with regard to monitoring safety during a clinical trial: "sponsors are expected to monitor all adverse events, including nonserious ones, during drug development." https://www.nejm.org/doi/pdf/10.1056/NEJMp1103464 (last visited Aug. 21, 2020).

categorized as "serious adverse reactions."[10] To wit, there are a myriad of post-licensure adverse reactions reported by consumers and physicians – which are also listed in the package inserts for one or more vaccines – that any individual living with these conditions would categorize as "serious"; yet the FDA, under its current guidelines, may not. These include, but are not limited to alopecia, autoimmune disease, lupus erythematosus, vasculitis, Bell's Palsy, hypotonia, migraine, myelitis, neuropathy, seizures, mental disorders, rhinitis, and vertigo.[11]

Given that in some trials SAEs and/or MAAEs are already being captured for 6 months or beyond, and efficacy is being tracked for 2 years, it appears foolhardy to not also capture *all* adverse events throughout the duration of each trial. If a COVID-19 Vaccine causes a systemic autoimmune issue to arise several months after vaccination, it would be irresponsible and unethical not to capture that reaction just because an autoimmune issue falls into the artificially defined zone of being an AE rather than what the FDA labels as an SAE or that which falls into the category of MAAEs (which must be part of an *unscheduled* visit with a doctor).

Given that none of the current study designs call for this long-term study of the AEs that result from the vaccines, we believe that none of the current studies will give the FDA or doctors a proper view of the actual medical effects of the vaccines. Therefore, mandating that everyone in New York receive the vaccines, when their adverse effects are not fully understood, is improper.

2. Documenting of Adverse Events and Reactions Should Last at Least Twenty-four Months for Adults, Thirty-six Months for Children, and Sixty Months for Infants and Toddlers

At a minimum, all AEs should be documented for each subject post-vaccination for at least: (i) twenty-four months for adults, (ii) thirty-six months for children, and (iii) sixty months for infants and toddlers. These minimal timeframes provide an opportunity to capture adverse and non-specific health issues that a novel COVID-19 Vaccine may cause. The current trial protocols do not meet this requirement.

The importance of capturing all potential health issues for the duration of the clinical trial can be seen in the designs of the clinical trials of numerous drugs, including for example, Enbrel[12],

[10] The FDA defines an adverse event to be "serious" if it results in one of the following specific outcomes: "death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect." FDA Guidance for Industry and Investigators, https://www.fda.gov/media/79394/download (last visited Aug. 21, 2020).

[11] *See* https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm (last visited Aug. 21, 2020). Also, the determination of whether an adverse reaction is a "serious adverse event" is typically left to the discretion of the sponsor of the clinical trial or the clinical investigators, who are paid by the sponsor, and therefore subject to bias. *See* 21 C.F.R. § 312.32, explaining that an adverse event may be categorized as "serious" if "in the view of either the investigator or sponsor, it results in any of the" listed outcomes.

[12] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf (last visited Aug. 21, 2020).

Lipitor[13], and Botox,[14] which had safety review periods of 6.6 years, 4.8 years, and 51 weeks respectively, with a placebo control group. As another example, the weight loss drug Belviq was safety tested in a placebo-controlled trial for two years before being licensed by the FDA in 2012.[15] Nevertheless, despite this two year period, in February 2020 the drug was voluntarily removed from the US market due to emerging data showing that people who had taken the drug as part of a large clinical trial had an increased occurrence of cancer five years later.[16]

The FDA states that the length of study for phase III clinical trials is typically "1 to 4 years"[17] and that the duration of a clinical trial should "reflect the product and target condition."[18] In accord with this guidance, and the fact that a COVID-19 vaccine will be an entirely novel product, the safety review period for adults should be at least 2 years. The need for this minimum safety review period following injection is further supported by the indications that the immunity conferred by a COVID-19 vaccine is not expected to last very long, potentially requiring repeated injections of the product during a person's life. Any mandate would not be for a one-time jab.

Moreover, the time frame for the safety review should be longer for minors, and in particular for infants and toddlers, because autoimmune, neurological, and developmental disorders will often not be diagnosed until after children are at least a few years old.[19] This is especially critical as Pfizer moves forward with participant as young as 12 years of age. Indeed, a 2019 review, authored by researchers at the FDA and Duke University, reviewed 306 pediatric clinical trials and found that short-term

> pediatric studies may not provide complete safety data across all critical periods of growth and development. This observation may be important because multiple periods of critical pediatric growth and development exist… Although the first 3 years of life are often considered more critical than older ages for brain development, biochemical studies of brain metabolism suggest that high brain

[13] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf (last visited Aug. 21, 2020).

[14] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf (last visited Aug. 21, 2020).

[15] *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf (last visited Aug. 21, 2020).

[16] *See* https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market (last visited Aug. 21, 2020); *see also* https://www.health.harvard.edu/blog/weight-loss-drug-belviq-recalled-2020040919439 (last visited Aug. 21, 2020).

[17] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited Aug. 21, 2020).

[18] https://www.fda.gov/media/102332/download (last visited Aug. 21, 2020).

[19] For example, according to the CDC, even for a common neurological disorder such as ADHD, "5 years of age was the average age of diagnosis for children reported as having severe ADHD." https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html (last visited Aug. 21, 2020). As another example, learning disabilities, a group of common developmental issues, are often "identified once a child is in school." https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed (last visited Aug. 21, 2020). Even for asthma, a very common autoimmune condition, whose symptoms are obvious, diagnosis can be difficult for children under 5 years of age because lung function tests aren't accurate before 5 years of age and "[s]ometimes a diagnosis can't be made until later, after months or even years of observing symptoms." https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513 (last visited Aug. 21, 2020).

> metabolic rates characteristic of early childhood may not decline to adult levels until ages 16 to 18 years, suggesting that the school-age and adolescent periods are equally critical periods of brain development. Given this information, even the longest trial duration identified in our study (364 weeks/7 years) does not completely evaluate potential critical stages of all pediatric growth and development periods.[20]

The FDA and Duke authors explained that, compared to licensing a drug for adults, "data on drug efficacy and safety in children may require an additional 6 years."[21] Because children have generally not suffered serious affects from COVID-19, the specific risks to children of any vaccine must be fully understood in order to weigh it against any potential benefit.

3. Trials Should Have Adequate Sample Size, Appropriately Powered, in Order to (i) Detect an Increase in Rare Adverse Events or Any Untoward Medical Occurrence, Whether or Not Considered Vaccine Related, and (ii) Determine That the Rate of Adverse Events From the Vaccine Will Not Exceed the Rate of Adverse Events Known to Occur From SARS-CoV-2 in the Group Under Review[22]

The study design for the Oxford/AstraZeneca Vaccine provides for only 30,000 individual study subjects, with only 20,000 individuals in the study group that will receive the nCoV-19 Vaccine and 10,000 individuals who will receive the placebo. The design for the BioNTech/Pfizer provides for less than 44,000 individuals (presumably less than 22,000 receiving the vaccine), the Moderna/NIAID design calls for 30,000 individuals (presumably only 15,000 individuals receiving the vaccine), and the Johnson & Johnson trial calls for 30,000 individuals in the vaccine group and 30,000 in the placebo group.

A Phase III trial for a COVID-19 Vaccine with even 30,000 subjects cannot produce an adequate safety profile for this product. SARS-CoV-2 poses a statistically insignificant risk of harm to children and young healthy adults. For this enormous cohort of the American population, the threshold for establishing that this vaccine is safer than the infection is exceedingly high and requires a highly powered trial. Even within so-called higher risk groups, the percent of individuals suffering serious health issues from SARS-CoV-2 is statistically small on a population level, which again demands a well-powered trial to assess the safety of the vaccine versus natural infection, because it is anticipated that this vaccine will be mandatory for most Americans.

In fact, 30,000 subjects in the group receiving the experimental vaccine is almost certainly not sufficient, according to a report from the Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research at the FDA, with regard to assessing its safety of a COVID-19

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[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526087/ (last visited Aug. 21, 2020).

[21] *Id*.

[22] For example, for children, the clinical trial should be properly sized and powered to determine that the vaccine is safer than a SARS-CoV-2 infection.

Vaccine for anything other than the groups with the highest risk of complications from SARS-CoV-2.[23]

The trial should have an adequate sample size, appropriately powered, in order to (i) detect an increase in rare adverse events or any untoward medical occurrence, whether or not considered vaccine related, and (ii) determine that the rate of adverse events from the vaccine will not exceed the rate of adverse events known to occur from SARS-CoV-2 in the group under review.

4. Participants Should Be Tested for T-cell Reactivity to SARS-CoV-2 Pre-vaccination and Post-vaccination

Clinical trial participants should be tested for T-cell reactivity to SARS-CoV-2 prior to vaccination and then again after vaccination. The trials for the leading COVID-19 vaccines are not conducting this testing. This testing is necessary because, as recently explained in the journal Nature Reviews Immunology by researchers at the Center for Infectious Disease and Vaccine Research at La Jolla Institute for Immunology, "if subjects with pre-existing reactivity were sorted unevenly in different vaccine dose groups, this might lead to erroneous conclusions. Obviously, this could be avoided by considering pre-existing immunity as a variable to be considered in trial design."[24]

Dr. Sette, a member of this group, further explained that "if you have 10 people that have reactivity and 10 people that don't have the pre-existing reactivity and you vaccinate them with a SARS CoV-2 vaccine, the ones that have the pre-existing immunity will respond faster or better to a vaccine ... So, we have been suggesting to anybody that is running vaccine trials to also measure T-cell response."[25]

B. The Oxford/AstraZeneca and Johnson & Johnson Petitions Request Additional Requirements

With regard to the Oxford/AstraZeneca and Johnson & Johnson Petitions, both concerning viral vector vaccines, ICAN additionally requested that the study design for the Phase III trials be amended to provide for the below criteria. If these criteria are not met, this is a factor that must mitigate against a recommendation for a mandate.

1. Germline Transmission Tests Should be Conducted for Male Participants

"The administration of certain gene transfer medicinal products to patients/subjects raises the possibility of vertical germline transmission of expression/transfer vector DNA. This raises ethical and safety concerns." [26] According to the European Medicines Agency, viral vectors may

[23] *See* https://pubmed.ncbi.nlm.nih.gov/11802587/ (last visited Aug. 21, 2020).

[24] https://www.nature.com/articles/s41577-020-0389-z (last visited Aug. 21, 2020).

[25] https://amp.cnn.com/cnn/2020/08/02/health/gupta-coronavirus-t-cell-cross-reactivity-immunity-wellness/index.html (last visited Aug. 21, 2020).

[26] *See* https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-non-clinical-testing-inadvertent-germline-transmission-gene-transfer-vectors_en.pdf (last visited Aug. 21, 2020).

be associated with a risk of vertical germline transmission of vector DNA.[27] The possibility exists with AstraZeneca's and Johnson & Johnson's novel viral-vector vaccines that they may result in modifications to the subject's germline genetic identity. Therefore, it is important to appropriately assess if there is a risk of inadvertent germline transmission and to inform individuals of that risk.

While "currently there are no non-invasive means to monitor women for germline transmission," male participants in the clinical trials can and should be monitored.[28] Germline transmission tests should be but, as of now, are not part of the clinical trial protocols."[29] This simple test would provide comfort that the vaccine is not having deleterious effects on the male germline. As of now, this testing is not part of the trials' protocols; this fact should weigh against a recommendation to mandate an inadequately tested vaccine..

2. HIV Incidence Should be Monitored and Evaluation of Target Tissues Where HIV Acquisition is Known to Occur is Needed

The AstraZeneca and Johnson & Johnson vaccines are viral vector vaccines. In past viral vector vaccine clinical trials, HIV incidence was higher in vaccinees than in placebo recipients.[30] This is an alarming occurrence and one that does not appear to have been acknowledged by the COVID-19 Vaccine manufacturers.

The Step Study was a phase II test of concept study of a trial HIV vaccine which consisted of adenovirus vectors. An interim analysis of HIV incidence was conducted with participants and showed that HIV incidence was **higher** in the vaccine group than in the placebo group. All additional vaccinations in the study were immediately halted. HIV rates appeared to be more than twice as high in vaccinees compared with placebo recipients in Ad5 seropositive men.[31]

In April 2014, Dr. Fauci co-authored an article which reviewed the Step Study data and, in its "Considerations for the future" section, recognized the potential risk for *any vector vaccine* to increase risk of HIV:

> **For non-HIV vaccine trials using vectors that induce strong T-cell immunity…** [potentially AstraZeneca and Johnson & Johnson's COVID-19 Vaccines] **it may be important to monitor for HIV acquisition**, depending on the target population. **In such studies where the population may be at risk of HIV exposure, HIV incidence should be monitored at the end of the study and for an appropriate follow-up period**.

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[27] *Id*.

[28] *Id*.

[29] *Id*.

[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2721012/ (November 29, 2008 article titled *Efficacy assessment of a cell-mediated immunity HIV-1 vaccine (the Step Study): a double-blind, randomised, placebo-controlled, test-of-concept trial*) (last visited Sept. 3, 2020).

[31] *Id*.

Although the AstraZeneca and Johnson & Johnson Vaccines are not specifically Ad-5 vector vaccines like the one in the Step Study (as they use different adenoviruses), the principle still stands: an adenovirus-based vaccine that may potentially "induce strong T-cell immunity" must be evaluated in order to determine whether or not it makes vacinees more susceptible to contracting HIV. In July 2015, Dr. Fauci, again discussing the Step data, stated: "A scientific symposium reviewing those data concluded that **vaccine-related immune activation might have led to increased susceptibility to infection.**"[32]

Recognizing Dr. Fauci's future considerations for all viral vector vaccines, it is critical that the incidence of HIV be assessed in trial participants at the end of the AstraZeneca and Johnson & Johnson COVID-19 Vaccines trials, and for an appropriate follow-up period after the trial, because these trials are using vectors that may induce strong T-cell immunity. As of now, no COVID-19 Vaccine clinical trial protocol calls for this assessment. Therefore, any mandate of a vaccine that may even potentially increase one's risk to HIV infection without proper testing is irresponsible at best.

C. The COVID-19 Vaccine Trials are Not Set Up to Demonstrate Reduction in Severe COVID-19, Hospitalizations, Deaths, or Transmission to Others

In addition to the safety concerns detailed above, the current Phase III trials for the COVID-19 Vaccines have serious flaws with regard to efficacy. Despite what the general public may believe, these trials are not designed to detect any improvement in severe cases of COVID-19, hospitalizations, or deaths nor are they set up to analyze whether or not the vaccines would prevent transmission of the virus from one individual to others.

The trials' endpoints include prevention of symptomatic disease in the vaccine recipient. In order to evaluate that endpoint, the trials will track recorded "events" of disease. However, the threshold to meet the criteria of such an "event" is exceedingly low. In the Moderna and Pfizer trials, for example, if a participant has a positive polymerase chain reaction test ("**PCR**") along with a cough, that participant would be counted as an "event." Once a trial reaches a certain number of "events", the trial is closer to seeking FDA approval or licensure. This effectively means that the efficacy of the vaccine will potentially be evaluated based on only mild cases of the disease. This will not shed light on any vaccine's ability to reduce or stop severe disease, hospitalization, or death. Because severe disease, hospitalization, and death are not occurring frequently, the time it might take to use these criteria as endpoints would extend the timeline of any clinical trial. In order to get results in a more timely fashion, the manufacturers appear to have lowered the threshold of the recorded "events" and therefore lowered the bar of what an "efficacious" vaccine means.

On top of only offering insight as to a vaccine's effect on mild disease, the clinical trials also do not call for interruption of transmission of the disease as a primary endpoint – what should arguably be the most important endpoint. This means that, aside from an individual choosing to

[32] https://science.sciencemag.org/content/349/6246/386.long (July 24, 2015 article titled *Toward an HIV vaccine: A scientific journey*) (emphasis added) (last visited Sept. 3, 2020).

take the vaccine in order to protect him/herself from mild COVID-19, there may be no potential benefit to the larger population, or at the very least the studies currently underway will not tell us whether the vaccines truly do prevent transmission. This is similar to the pertussis vaccine which offers a reduction in symptoms for vacinees who become infected with pertussis, but does not offer protection from infection nor does it prevent vacinees from transmitting pertussis to others. The fact that a vaccine may lessen the severity of symptoms in a recipient (and be considered "effective" for that measure alone) cannot be confounded with its ability to prevent infection and transmission.

The Chief Medical Officer at Moderna, Tal Zaks, openly admitted that the "trial will not demonstrate prevention of transmission."[33] When speaking with *The BMJ*, Zaks explained that "in order to [demonstrate prevention of transmission] you have to swab people twice a week for very long periods and that becomes operationally untenable."[34]

As Peter Doshi, Associate Editor at *The BMJ*, further reported: "COVID-19 vaccine trials are currently designed to tabulate final efficacy results once 150 to 160 trial participants develop symptomatic COVID-19 – and most trials have specified at least one interim analysis allowing for the trials to end with even fewer data accrued."[35] Eric Topol, from Medscape, criticized this procedure, saying: "These numbers seem totally out of line with what would be considered stopping rules…you're talking about giving a vaccine with any of these programmes to tens of millions of people. And you're going to base that on 100 events?"[36]

As Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine in Houston, said: "Ideally, you want an antiviral vaccine to do two things…first, reduce the likelihood you will get severely ill and go to the hospital, and two, prevent infection and therefore interrupt disease transmission."[37] The four frontrunner vaccines' Phase III trial protocols do not analyze, and certainly do not guarantee, either of those things.

II. The Conflicts of Interest Within the Data Safety & Monitoring Boards of COVID-19 Vaccines

Compounding the issues with the clinical trial protocols is the concern that the individuals overseeing these very trials – those tasked with ensuring the vaccines' safety and efficacy based on the trial results – are not at all independent of the pharmaceutical industry and are, in fact, conflicted. If the NYSBA were to issue a recommendation for a mandate based on these individuals' recommendation and approval of a COVID-19 Vaccine believing that they are independent and removed from any conflict, that would be a false premise. Delegates should be

[33] https://www.bmj.com/content/371/bmj.m4037.

[34] *Id*.

[35] *Id*.

[36] *Id*.

[37] https://www.msn.com/en-us/health/medical/those-coronavirus-vaccines-leading-the-race-don-t-ditch-the-masks-quite-yet/ar-BB17mN6n.

aware of these individuals' conflicts and make a determination of "independence" and reliability themselves.

ICAN has recently written to numerous public health officials, including Dr. Fauci, Secretary Azar, and Dr. Atlas, to express serious issues it has uncovered regarding the conflicts within the Data and Safety Monitoring Boards ("**DSMBs**") that are overseeing the clinical trials for the four experimental COVID-19 vaccines.

The clinical trials for three of these experimental vaccines – the ones to be sold by AstraZeneca, Moderna, and Johnson & Johnson – are being overseen by a DSMB created by NIAID (the "**NIAID DSMB**"). The clinical trial for Pfizer's experimental vaccine is being overseen by a different DSMB (the "**Pfizer DSMB**", and together with the NIAID DSMB, "**the DSMBs**"). Public health experts have repeatedly told the American public that these board members are independent of any influence from the pharmaceutical industry. However, ICAN has learned that the two members whom it could identify have significant ties to various pharmaceutical companies, which raises significant concerns regarding the independence of the DSMBs.

The members of the DSMBs were selected in secret. They meet in secret. Their identities are supposed to remain a secret. Indeed, the members of the DSMBs have remained a secret, with the exception of two members. The chairperson of the NIAID DSMB's identity was apparently mistakenly released by his university in an announcement that has now been scrubbed from its website. The article titled, *These Secret Safety Panels Will Pick the COVID Vaccine Winners*, reported about the announcement, which disclosed that Dr. Richard Whitley was appointed as chair of the NIAID DSMB.[38] As for the Pfizer DSMB, made up of only five individuals, one of its members, Dr. Kathryn Edwards, was apparently mistakenly revealed in a CBS article.[39] The names of the other members of the DSMBs have not been made public, despite the public's call for and the manufacturers' and agencies' vows of transparency.[40]

ICAN's research regarding the two members of the DSMBs it could identify raises extremely troubling concerns regarding the selection of candidates for the DSMBs. The process for selecting these individuals certainly lacked transparency and their selection could only occur by turning a blind eye to their extremely troubling and blatant conflicts with pharmaceutical companies detailed in this letter. For example, one or both of these two doctors have been, among other things, consultants for Gilead Science, AstraZeneca, GlaxoSmithKline, Merck, Sanofi, Sequirus, La Roche, Allergan, SmithKline Beecham, Wyeth Lederle, Moderna, X4 Pharmaceuticals, Novartis, Fermavir, and Inhibitex; advisors to Merck, Bionet, GSK, Pfizer, and Gilead; and paid speakers for Connaught, Lederle-Praxis, Wyeth Lederle, Glaxo, and Novartis,

[38] https://khn.org/news/these-secret-safety-panels-will-pick-the-covid-vaccine-winners/.

[39] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

[40] As explained by Bioethicist Art Caplan, when speaking of the COVID-19 DSMBs, "They're very powerful. They're key guardians of science and safety and are as important if not more important than the FDA" and that while DSMB members are typically not disclosed, he explains that with regard to COVID-19 vaccines, "We need to know if we can trust the vaccine, so the more transparency the better." https://www.cnn.com/2020/10/03/health/dsmb-role-coronavirus-vaccine-trial/index.html.

among others. These scientists have had duties to these companies as consultants and advisors, have been personally financially supported by them, and have been their mouthpieces to the public. These conflicts raise serious ethical issues, render any decision by the DSMBs unreliable.

A. Government Officials Assure the American Public that the DSMBs are Independent

The American public is constantly assured by Dr. Fauci, Mr. Azar, and other public health officials that the DSMB members are independent of pharmaceutical companies. They have provided repeated assurances that Americans can trust the COVID-19 vaccine trials because the members of the DSMBs overseeing these trials have no conflicts with pharmaceutical companies and can make objective decisions. For example, Dr. Fauci recently told the public that: "[P]eople need to understand that **an independent body**, the Data and Safety Monitoring Board, is **beholden to no one**, not to the president, **not to the vaccine companies**, not to the FDA. Not to me."[41]

In fact, Dr. Fauci has been loudly and vigorously beating the drum that Americans can have confidence in a COVID-19 vaccine because there is an "independent board," free of entanglements with pharmaceutical companies. The following are but a few examples from the last month, September 2020, in which Dr. Fauci repeated this assurance to the American public:

- On September 2, 2020, in a STAT News interview: "It's up to the DSMB, in their judgment, to balance the safety issue, the efficacy issue, and the duration of the trial issue…And that's the reason why **they're an independent group**. **They are not the company** because obviously the company is going to want to get their product approved as quickly as possible."[42]

- On September 11, 2020, in a *Newsweek* interview: "There are a number of checkpoints in that process [of releasing a vaccine] that would make it very difficult for politics to have an influence on whether a vaccine is approved for use before it was shown truly to be safe and effective. The accumulation of data and **the analysis of data is unbiased**. **An independent group** called a Data and Safety Monitoring Board is associated with every clinical trial that has NIH [National Institutes of Health] fingerprints on it."[43]

- On September 21, 2020, during a live townhall hosted by Navajo Nation President Jonathan Nez, addressing the safety of the Pfizer vaccine trials: "One of the assurances that you are dealing with something that is safe is that each vaccine that is tested has a Data and Safety Monitoring Board,

[41] https://www.vox.com/21454359/fauci-rand-paul-covid-19-vaccine-trust-cdc-fda (emphasis added).

[42] https://www.statnews.com/2020/09/02/experts-see-a-chance-for-a-covid-19-vaccine-approval-this-fall-if-its-done-right/.

[43] https://www.newsweek.com/dr-fauci-would-bet-10-cents-trump-having-covid-19-vaccine-november-december-1531370.

which is **an independent group** that looks at the data to determine at which point you can say that the vaccine is effective."[44]

- On September 24, 2020, during a Facebook Live interview with New Jersey Governor Phil Murphy, when addressing the "mixed messages" that are being sent regarding whether a COVID-19 vaccine is safe and effective: "with every vaccine trial, there's a thing called a data and safety monitoring board which is **an independent group** of scientists, vaccinologists, ethicists and statisticians who are the only ones that are allowed to see the data from the [vaccine's clinical] trial."[45]

Secretary Azar has similarly recognized the issue of vaccine confidence and has provided the same assurance to the American people. On September 3, 2020, Secretary Azar acknowledged to CBS that, "We already have a significant challenge in this country with vaccine hesitancy, and efforts to undermine confidence in a vaccine that would come hurt in terms of people willing to take a vaccine once it comes through."[46] Secretary Azar further told the public that any vaccine data "will be reviewed by a Data and Safety Monitoring Board, that's **an independent board**, and then that data, at the appropriate time will go to the FDA."[47]

Despite these assurances to the public and the clear principles underlying the need for an independent DSMB, the investigation conducted by ICAN into the chair of the NIAID DSMB and the one member it could identify for Pfizer's DSMB reveals that they have conflicts with pharmaceutical companies that are shocking to the conscience. They render the claims regarding a supposed "independent" DSMB for COVID-19 vaccines false. There are thousands of scientists in the world – choosing those that are pharmaceutical foot-soldiers undermines the purpose of a DSMB. This course should be corrected by replacing these individuals with those free of all pharmaceutical company ties, past and present, and whose interests are not conflicted by the industry for whom they have acted – and will continue to act – as advisors, consultants, fiduciaries, advocates, and public speakers. However, ICAN has seen no steps taken to right this wrong.

[44] https://navajotimes.com/coronavirus-updates/fauci-navajo-a-model-for-containing-coronavirus/.

[45] https://www.facebook.com/governorphilmurphy/videos/live-with-dr-anthony-fauci/631905121047750/.

[46] https://www.forbes.com/sites/carlieporterfield/2020/09/03/azar-denies-november-goal-for-vaccine-preparedness-is-tied-to-presidential-election/#57f9cec57f73.

[47] Secretary Azar then gave assurances that any decision to release a vaccine in the U.S. would be based on the data and the "FDA's gold standards." https://www.cbsnews.com/news/alex-azar-coronavirus-vaccine-distribution/. Even the National Institutes of Health's "Data and Safety Monitoring Board (DSMB) Guidelines" explain that "no member [of a DSM] should have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB."[47] The FDA provides similar guidance, explaining that "[c]onflicts of interest deserve special consideration in choosing individuals to serve on a [DSMB]." https://www.fda.gov/media/75398/download.

B. Dr. Richard Whitley

The NIAID DSMB's chairperson, Dr. Whitley, has long-standing and disqualifying financial and employment entanglements with many pharmaceutical companies, including those developing a COVID-19 vaccine.

In the last six years alone, Dr. Whitley has been a consultant for Gilead Science, AstraZeneca, GlaxoSmithKline, Merck, Sanofi, Sequirus, La Roche, and Allergan.[48] He personally was paid over $2.6 million for the work he performed for these companies during this period.[49] During the last six years, Dr. Whitley was also wined-and-dined on the tab of these companies to over 240 meals, for which these companies paid $15,597, including 42 meals with a bill above $100.[50] During the last six years, Dr. Whitley also took 281 trips around the country and the world, paid for by these companies – totaling $172,992.51 – including to Belgium, Bahamas, Japan, Canada, and South Africa.[51] Dr. Whitley has sat for well over a decade on the Board of Directors of a pharmaceutical company and is reported to own over 68,000 shares of the pharmaceutical company Gilead.[52] He has also received unknown amounts from Novartis and other pharmaceutical companies in consulting or lecture fees.[53]

Likewise, Dr. Whitley has been on the speakers' bureau for GlaxoSmithKline and Novartis, both of which are developing COVID-19 vaccines.[54] The Pew Charitable Trusts' guidance entitled *Conflict of Interest Policies for Academic Medical Centers* explains that: "Faculty who participate in speakers' bureaus are de facto 'marketers in academic robes' and lend a patina of academic endorsement to the promotional agenda of the sponsoring companies, which compromises academic integrity. Furthermore, promotional speakers are poor role models for trainees."[55] Similarly, in an article published in the *Journal of Law, Medicine & Ethics* by professors and deans from the Tufts University School of Medicine – including the Dean and Professor of Public Health and Community Medicine and the Assistant Dean for Conflicts of Interest Administration – they explain regarding doctors, like Dr. Whitley, that serve on pharmaceutical company speakers' bureaus that:

> [N]umerous medical associations, such as the Association of American Medical Colleges (AAMC), the American Board of Internal Medicine (ABIM) and the Institute on Medicine as a

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[48] https://projects.propublica.org/d4d-archive/search?utf8=%E2%9C%93&term=Richard+James+Whitley&state%5Bid%5D=&company%5Bid%5D=&period%5B%5D=&services%5B%5D=; https://openpaymentsdata.cms.gov/physician/495549.

[49] *Id.*

[50] https://openpaymentsdata.cms.gov/physician/495549.

[51] *Id.*

[52] https://www.sec.gov/Archives/edgar/data/882095/000119312512123423/d317498ddef14a.htm.

[53] https://pubmed.ncbi.nlm.nih.gov/17143845/; https://jamanetwork.com/journals/jama/article-abstract/185429.

[54] https://jamanetwork.com/journals/jama/article-abstract/185429; https://cspinet.org/new/200701181.html.

[55] https://www.pewtrusts.org/-/media/legacy/uploadedfiles/phg/content_level_pages/reports/coibestpracticesreportpdf.pdf.

Profession (IMAP), and government bodies such as the Institute of Medicine (IOM) have recommended that medical schools and teaching hospitals prohibit or strongly discourage faculty from participating in so-called industry "Speakers' Bureaus" …

Pharmaceutical company Speakers' Bureaus are a marketing enterprise wherein physicians and other professionals are engaged and trained by one or more companies to give a lecture about a medical condition or drug treatment to an audience of prescribers toward the end of promoting the company's drug which treats that condition. These speakers are generally required to use company-created or company approved slides and are expected, prior to their presentation, to collaborate and review the slides with the company medical officers. This process is intended to focus the speaker on the most positive aspects of a drug, thus increasing the familiarity and appeal of that drug to the speaker — as well as the company's marketing message. It is widely argued that **physicians who participate in Speakers' Bureaus are essentially just paid marketers or spokespersons for industry who use, indeed exploit, their roles as physician leaders to influence their colleagues to prescribe the sponsor's product.** The sentiment that Speakers' Bureaus are promotional rather than educational is reinforced by the fact that the Bureaus are funded through pharmaceutical companies' marketing budgets. …

In a recent study of physicians at continuing medical education conferences, 73 percent of physicians reportedly perceived that faculty members who participate in commercial Speakers' Bureaus are moderately-to-substantially biased in favor of the company's product. Indeed, numerous studies have shown that payments from a pharmaceutical company, even in the form of small gifts of minimal value, influence physicians' prescribing habits in favor of the company's drug. Even physicians who reportedly believe they are impervious to influence by gifts and fees, or who view themselves as educators and "thought leaders" when they are paid to speak about a particular drug, have been shown to write more prescriptions for the drug after speaking about the product. …

[P]harmaceutical companies' understanding of how gifts influence physicians has caused some of them to prohibit their own employees, including their physicians, from accepting even small gifts.[56]

[56] https://pubmed.ncbi.nlm.nih.gov/22789048/ (emphasis added).

Dr. Whitley also has a history of failing to disclose his conflicts of interest. He had to issue a public apology in 2010 for failing to disclose his extensive pharmaceutical company conflicts in an article he published in the Journal of the American Medical Association ("**JAMA**") where he had to publicly admit that he "truly regret[ted] [his] failure to report these disclosures in the articles and letter reply and apologize[d] to both the editors and the readers of JAMA for this."[57] In this apology, Dr. Whitley even said he is "a firm believer in transparency and believe[s] that it is mandatory in academic efforts."[58] He even thereafter stated that, "I think we need to teach people…how to interact with drug companies so everything is totally transparent...for patients, for colleagues, for administrators and to the community."[59]

Dr. Whitley has not learned from this "mistake" nor does it appear his apology was sincere since he has continued to fail to disclose his extensive conflicts thereafter. For example, on March 24, 2020, he gave a public presentation to the Bio Coronavirus Collaborative Initiative Summit, regarding COVID-19, including discussing treatments. While that presentation discloses that Dr. Whitley is a "distinguished Professor of Pediatrics, Vice Chair of the Department of Pediatrics, and Co-Division Director of Pediatric Infectious Diseases, University of Alabama at Birmingham," Dr. Whitley does not disclose a single conflict with any pharmaceutical company, including his conflicts with pharmaceutical companies developing products for COVID-19.

Only those wearing blinders could give Dr. Whitley the label "independent." To head the "independent" DSMB, Dr. Fauci could have selected from a sea of potential scientists, many of whom have never consulted for a pharmaceutical company, were never on a pharmaceutical company speakers' bureau, and have not had hundreds of meals and dozens of exotic trips paid for by pharmaceutical companies. Instead he chose Dr. Whitley. Compounding this debasement of the term "independent", Dr. Fauci misrepresented to the American people that "there's a thing called a data and safety monitoring board which is **an independent group** of scientists"[60] and that "an **independent body**, the Data and Safety Monitoring Board, is **beholden to no one**…**not to the vaccine companies**, not to the FDA. Not to me."[61] Dr. Whitley's numerous financial ties to pharmaceutical companies seriously raise questions regarding Dr. Fauci's definition of "independent."

C. Dr. Kathryn Edwards

Like Dr. Whitley, Dr. Kathryn Edwards has long-standing and disqualifying financial and employment entanglements with many of the companies developing a COVID-19 vaccine. Dr. Edwards is a professor of pediatrics in the division of infectious diseases at Vanderbilt University

[57] https://jamanetwork.com/journals/jama/article-abstract/185429.

[58] *Id*.

[59] https://www.al.com/news/birmingham/2015/07/some_uab_faculty_receive_hefty.html.

[60] https://www.facebook.com/governorphilmurphy/videos/live-with-dr-anthony-fauci/631905121047750/.

[61] https://www.vox.com/21454359/fauci-rand-paul-covid-19-vaccine-trust-cdc-fda.

School of Medicine, where she is also vice-chair for clinical research.[62] CBS reported that Dr. Edwards is sitting on Pfizer's DSMB.[63]

Incredibly, Dr. Edwards was a paid advisor to Pfizer directly before joining its DSMB for the COVID-19 vaccine.[64] Meaning, she had duties to this company, in their employ, up until she then apparently relinquished this position to become a member of the "independent" DSMB overseeing Pfizer's clinical trial. This alone makes a mockery of the notion that this DSMB is "independent."

Dr. Edwards's other conflicts with pharmaceutical companies abound. Dr. Edwards has been an advisor and consultant to and has received personal fees from Merck.[65] She has received payments for giving lectures and research funding from GSK and has been on its advisory board.[66] She has been a consultant for and has received both tens of thousands of dollars in payments for lectures as well as research funding from Sanofi.[67] Sanofi has even paid for trips that Dr. Edwards has taken to, among other destinations: Paris, France; Dublin, Ireland; Amsterdam, Netherlands; and Cancun, Mexico.[68]

Dr. Edwards has also been a consultant for Connaught, Smith-Kline Beecham, Wyeth Lederle, Moderna, Roche, and X4 Pharmaceuticals.[69] She has been an advisor to Bionet[70] and has received research funding from Wyeth Lederle.[71] Like Dr. Whitley, she has also been on the speakers' bureaus for pharmaceutical companies, including Connaught and Wyeth Lederle.[72]

Dr. Edwards has also failed to disclose these incestuous conflicts with pharmaceutical companies. For example, on July 29, 2020, she provided the only presentation to date focused on the safety of COVID-19 vaccines given to the Advisory Committee on Immunization Practices ("**ACIP**") titled, "COVID-19 Vaccine Safety Considerations.[73] In her accompanying presentation materials, Dr. Edwards disclosed that she is the Principal Investigator of the Centers for Disease

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[62] https://www.vumc.org/viiii/person/kathryn-m-edwards-md.

[63] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

[64] https://pubmed.ncbi.nlm.nih.gov/32338708/ ("K.E. serves as a scientific advisor for … Pfizer"); https://pubmed.ncbi.nlm.nih.gov/31971685/ ("Dr. Edwards reports … personal fees from Pfizer").

[65] https://pubmed.ncbi.nlm.nih.gov/30938299/.

[66] https://openpaymentsdata.cms.gov/physician/651167; https://academic.oup.com/jid/article/222/8/1413/5510417.

[67] https://www.nejm.org/doi/10.1056/NEJMoa050824; https://openpaymentsdata.cms.gov/physician/651167.

[68] https://openpaymentsdata.cms.gov/physician/651167.

[69] https://pubmed.ncbi.nlm.nih.gov/32753370/; https://pedsinreview.aappublications.org/content/19/2/68; https://pubmed.ncbi.nlm.nih.gov/10617749/.

[70] https://pubmed.ncbi.nlm.nih.gov/32753370/.

[71] https://pubmed.ncbi.nlm.nih.gov/10617749/.

[72] https://pedsinreview.aappublications.org/content/19/2/68.

[73] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-03-Edwards-508.pdf.

Control and Prevention ("**CDC**") funded Clinical Immunization Safety Assessment Project.[74] Yet, she did not disclose any of her aforementioned conflicts with pharmaceutical companies, including those developing COVID-19 vaccines.[75]

Dr. Edwards also answered questions following her presentation and discussed the role of DSMBs. She stated that there would be an active effort by DSMBs to look at each adverse event as Phase III studies are rolled out and that these DSMBs are independent of manufacturers and investigators.[76] In discussing potential adverse reactions to a COVID-19 vaccine at the ACIP meeting, Dr. Edwards stated that, "people need to understand that if there is a signal, we want to see it" and that the DSMBs will investigate pre-licensure.[77] At no point in her presentation or discussion following the presentation did Dr. Edwards disclose that she has received payments and funds from numerous pharmaceutical companies throughout her career or that she currently sat on a DSMB.[78]

D. The Need for Transparency

Dr. Fauci and other federal public health officials have repeatedly asserted in the national media that a coronavirus vaccine is critical to controlling infections and morbidity from SARS-CoV-2. They have also expressed that once a vaccine is licensed, its success will depend on the public's willingness to take the vaccine. But, recent polls reflect that a significant portion of Americans will not consent to this vaccine. Hence, more so than with other vaccines, overcoming vaccine hesitancy regarding a COVID-19 vaccine in the current climate demands that the process for evaluating its safety and efficacy during its clinical trials be transparent and that those involved in this process be free from financial and other conflicts of interest. This is especially true of a vaccine developed at "warp speed."

Addressing potential conflicts of interest is critical to assure the American public that decisions pertaining to any coronavirus vaccine are made with a sound, independent scientific basis, not for political reasons or for the financial benefit of any individual or company. ICAN asked that government health officials address these aforementioned issues in order to avoid further erosion of confidence in the NIH, in NIAID, and in Operation Warp Speed. NYSBA should likewise make its recommendation for or against a COVID-19 Vaccine mandate based on all of the facts in order to avoid erosion of confidence in the NYSBA.

III. The Conflicts of Interest Within the National Institutes of Health and the COVID-19 Vaccines

In addition to grave issues with the clinical trials and concerns about the independence of those charged with determining the safety and efficacy of said trials, further conflicts of interest

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[74] *Id*.

[75] https://www.youtube.com/watch?v=vftiaq-yZBs&t=3963s.

[76] *Id.*

[77] *Id.*

[78] *Id.*

exist within NIH: when government officials will profit from the sale of a product, there is cause for concern regarding their licensure and promotion of that product.

One of the first COVID-19 Vaccines to begin trials in the United States was mRNA-1273.[79] This experimental vaccine was developed by Dr. Anthony Fauci's NIAID along with biotech company, Moderna Inc.[80] If this vaccine is licensed, NIAID and at least six individuals within NIAID stand to each earn **millions of dollars** from is sales.[81]

To receive a share of the profit from the sale of mRNA-1273, inventors of this product within NIAID submitted an Employee Invention Report to the NIH Office of Technology Transfer.[82] Each inventor stands to receive a personal payment of up to $150k annually from the sales of this product.[83] The NIH also stands to earn millions of dollars in revenue from the sale of mRNA-1273 in addition to what its members earn personally.[84]

Moderna will be the company selling mRNA-1273 to the public. Moderna will pay a license fee to NIAID[85] for its patents used to develop mRNA-1273. The NIAID[86] then remits a portion of those fees **directly to the inventors within NIAID** that developed those patents.[87]

There are two patents on which individuals in NIAID are listed as inventors which relate to development of mRNA-1273.[88] The first is patent application number 62/412,703 entitled *Prefusion Coronavirus Spike Proteins and Their Use*[89] and the second is patent application number 62/972,886 entitled *2019-nCoV Vaccine*[90]. The following are the individuals in NIAID that are listed as inventors on one or both of these patents:

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[79] https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[80] https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[81] https://www.ott.nih.gov/royalty/information-nih-inventors; https://science.sciencemag.org/content/early/2020/02/19/science.abb2507?versioned=true ("Competing interests").

[82] https://www.ott.nih.gov/resources.

[83] https://www.ott.nih.gov/royalty/information-nih-inventors.

[84] https://www.ott.nih.gov/resources.

[85] The payments may be remitted directly to NIAID, its parent agency NIH, its parent department HHS, or some entity related thereto.

[86] The payments are sent from NIAID, its parent agency NIH, or some entity related thereto.

[87] https://www.ott.nih.gov/royalty/information-nih-inventors.

[88] https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true (see "Competing interests" on page 4).

[89] http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&f=G&l=50&d=PG01&S1=344,774&OS=344,774&RS=344,774; https://www.ott.nih.gov/technology/e-234-2016.

[90] https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true (see "Competing interests" on page 4).

- Barney Graham, Deputy Director, NIAID Vaccine Research Center[91]
- Kizzmekia Shanta Corbett, Scientific Lead, NIAID's Coronavirus Vaccine Program[92]
- Michael Gordon Joyce, NIAID[93]
- Hadi Yassine, NIAID[94]
- Masaru Kanekiyo, NIAID[95]
- Olubukola Abiona, NIAID[96]

Based on the foregoing, these individuals within Dr. Fauci's NIAID, and their heirs,[97] will each potentially earn millions of dollars personally from sales of mRNA-1273 over the next twenty years. NIAID also stands to earn millions annually from the sale of this vaccine.

Given the potentially significant personal financial interests of individuals within NIAID, it may not be surprising that NIAID is using taxpayer dollars to sponsor, assume responsibility for, and perform the first clinical trial of this vaccine.[98] There is a clear conflict in having NIAID, whose members stand to potentially earn millions of dollars from this vaccine, overseeing and conducting the clinical trial for mRNA-1273. This clinical trial information is what NIAID's sister agency, the FDA, will then rely upon to license the mRNA-1732 vaccine for public use.

NIAID's parent department has also awarded $483 million to accelerate development of mRNA-1273, including to "fund the development of mRNA-1273 to FDA licensure and manufacturing process scale-up to enable large-scale production in 2020 [before licensure is granted]."[99] NIAID's parent department has also granted those developing and selling this product broad immunity from liability for injuries.[100]

Dr. Fauci has been tirelessly promoting the mRNA-1273 vaccine that will potentially make members of his agency millionaires and drive millions more into his agency. It should not be that

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[91] https://www.niaid.nih.gov/research/barney-graham-md-phd; https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0010633378; https://www.nytimes.com/2020/01/28/health/coronavirus-vaccine.html.

[92] https://www.med.unc.edu/microimm/former-mi-graduate-student-kizzmekia-corbett-developing-a-vaccine-against-the-coronavirus/; https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0012686509; https://www.linkedin.com/in/kizzmekiacorbett/.

[93] https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0012508859 https://www.hivresearch.org/our-scientists/m-gordon-joyce-bsc-hons-phd.

[94] https://www.niaid.nih.gov/research/barney-graham-md-phd.

[95] https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0012877868.

[96] https://ned.nih.gov/search/ViewDetails.aspx?NIHID=2002358423.

[97] https://www.ott.nih.gov/royalty/information-nih-inventors#11.

[98] https://clinicaltrials.gov/ct2/show/NCT04283461; https://projectreporter.nih.gov/project_info_history.cfm?aid=10110093&icde=49376321; https://projectreporter.nih.gov/project_info_description.cfm?aid=9872016&icde=49376321.

[99] https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19; https://investors.modernatx.com/node/8671/pdf.

[100] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

the federal department responsible for testing and licensing a product includes individuals that stand to earn millions of dollars from selling that product. It creates conflicts of interest that can cloud the vision of the most clear-eyed individuals. Therefore, the simple fact that the FDA or NIH has approved a vaccine does not necessarily mean it is safe.

IV. Immunity to Liability of COVID-19 Vaccines

If ICAN's fears come to fruition and a potentially unsafe or ineffective vaccine is released to market (due to sub-standard clinical trials, a conflicted DSMB, and/or driven by selfish profit motives), those injured by such a vaccine have effectively been robbed of all rights to hold the vaccine manufacturers (or vaccine administrators) liable.

The Secretary of the United States Department of Health & Human Services (**HHS**), Alex M. Azar III, has granted the companies selling (and those involved in virtually any other activity related to any COVID-19 vaccine) immunity from liability for any injuries caused by these products. Notably, prior to his current position, Secretary Azar was a senior executive for a major pharmaceutical company, Eli Lilly and Company, from 2007 to 2017.

Secretary Azar has issued a "Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19." (85 FR 15198). It provides that those that "prescribe, administer, deliver, distribute or dispense" and the "manufacturers [and] distributors" of "any vaccine, used to treat, … prevent or mitigate COVID-19" shall enjoy "[l]iablity immunity ," including, "from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a [COVID-19 vaccine]." (*Id.*; 42 U.S.C. § 247d-6d.)

An integral driver of consumer safety is the potential and actual liability companies face if their product causes harm. To assure consumers that a pharmaceutical company stands behind the safety of its vaccine product, ICAN made a public request that each pharmaceutical company formally declare that it waives the immunity from liability granted by HHS for injuries caused by COVID-19 vaccine.

Waiving this immunity would provide the standard and minimal level of product safety assurance consumers expect. If a company will not bear the risk of having to pay for injuries caused by its product, it should be understandable that consumers will not want to bear the risk of being injected with that product.

An AstraZeneca senior executive team member acknowledged the very real potential of side effects being discovered years down the line. In explaining why AstraZeneca needs protection from future product liability claims against its COVID-19 vaccine, Ruud Dobber stated: "This is a unique situation where we as a company simply cannot take the risk if in ... four years the vaccine is showing side effects."[101] On the other hand, Americans cannot and should not be obligated to

[101] https://in.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idINKCN24V2EN (last visited Aug. 21, 2020).

take that risk, especially if they are never given an opportunity to choose whether to take that product. AstraZeneca's risk is financial. Vaccine recipients' risk is of a much higher stake.

To date, **not one of these pharmaceutical companies that have publicly announced that they will stand-behind their product have agreed to waive immunity from liability** for injuries caused by their COVID-19 vaccine. This immunity raises two important issues for the NYSBA to take into consideration. First, the pharmaceutical companies developing these products have every financial incentive to get their product to market quickly, but literally no financial incentive to ensure the safety of that product. Second, if New York mandates administration of the COVID-19 vaccine, a certain percentage of people who receive the vaccine will suffer adverse events, and those people will be unable to hold the manufacturers liable. Thus, the decision to mandate this product will inevitably be a decision to consigning a certain percentage of New Yorkers to a potentially life altering adverse condition for which will have limited or no options to be appropriately compensated.

V. Natural Immunity to SARS-CoV-2

A significant percentage of Americans have now been exposed to and have had the SARS-CoV-2 infection. Studies have shown that the herd immunity threshold for COVID-19 is likely between 10% and 20%.[102] If accurate, this means that we are close to reaching that threshold in America and have already met that threshold in New York.[103]

The explanation for the lower threshold of herd immunity is the fact that we have all likely been exposed (and re-exposed) to numerous other coronaviruses, including the common cold, and our T-cells therefore carry immunity to this coronavirus.[104] The human body knows how to develop immunity to newly emerging viruses due to eons of evolution of the adaptive branch of the immune system in all vertebrates. The adaptive immune system consists of an enormously diverse repertoire of B cells (precursors of antibody-secreting plasma cells) and T cells with a nearly unlimited capacity to recognize and 'adapt' to previously unseen pathogens.

Immunologic studies using human subjects who have had the SARS-CoV-2 infection (COVID-19) showed that patients have indeed developed sustained neutralizing antibodies[105] and

[102] *See* https://www.medrxiv.org/content/10.1101/2020.07.23.20160762v1.full.pdf ("Our inferences result in herd immunity thresholds around 10-20%…these findings have profound consequences for the governance of the current pandemic given that some populations may be close to achieving herd immunity despite being under more or less strict social distancing measures.").

[103] *See* https://covid.cdc.gov/covid-data-tracker/#national-lab showing 22.5% estimated population of New York infected of population.

[104] *See* https://reaction.life/we-may-already-have-herd-immunity-an-interview-with-professor-sunetra-gupta/ (Professor Sunetra Gupta, a theoretical epidemiologist at Oxford University, explains: "What I didn't anticipate was that some of our responses to previous exposure to seasonal coronaviruses might actually protect us from infection. It's one thing to get infected and not ill, but what the new studies are showing is that people are actually fighting off infection. So at an even more basic level, the pre-existing antibodies or T-cell responses against coronaviruses seem to protect against infection, not just the outcome of infection."

[105] https://pubmed.ncbi.nlm.nih.gov/32743600/; https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1.

robust T-cell memory[106] to the virus. This means that the human adaptive immune system, after being successfully engaged in the immune response to SARS-CoV-2, will be capable of recognizing the virus in the future.

Immunity that has been acquired naturally is the best form of immunity to any virus. Vaccines, by their design, attempt only to emulate the immunity created by a natural infection. Nonetheless, they have never achieved the same level of protection afforded by actually having a virus.

Indeed, every single vaccine for a virus confers an inferior immunity to having had the actual virus. Even the best vaccines do not confer immunity to all recipients, the temporary immunity created by any vaccine typically wanes over time, and some vaccines cannot even protect from viral carriage and shedding. For example, Dr. Stanley Plotkin, known by many as "the world's leading authority on vaccines," when asked, "[s]o a person vaccinated with IPV can still become infected and transmit polio virus, correct?" Dr. Plotkin answered, "Yes."[107] And when discussing the vaccine for mumps, Dr. Plotkin states, "[u]nfortunately, the efficacy diminishes with time, and that has caused a problem in universities that have outbreaks of mumps."[108]

There is no reason to expect that vaccine candidates currently in development for SARS-CoV-2 will be any better in this respect. In animal studies, the SARS-CoV-2 vaccine candidates could not fully block viral infection and replication in the nose of monkeys upon viral challenge.[109] In contrast, the SARS-CoV-2 infection of monkeys completely prevented further re-infection at any site tested (by nasal/throat/anal swabs).[110]

Consistent with the study that demonstrated no re-infection of monkeys with SARS-CoV-2 upon deliberate re-exposure, in the ten months since the SARS-CoV-2 virus first appeared in this country, doctors and scientists have not found adequate evidence that would support an argument that those already exposed to SARS-CoV-2 are at risk of becoming re-infected and transmitting SARS-CoV-2. This is despite the entire world's scientific community turning its attention to studying this virus.[111]

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[106] https://pubmed.ncbi.nlm.nih.gov/32979941/.

[107] Plotkin Deposition at 381:22-24.

[108] Plotkin Deposition at 384:12-14.

[109] https://www.nejm.org/doi/full/10.1056/NEJMoa2024671; https://pubmed.ncbi.nlm.nih.gov/32511340.

[110] https://pubmed.ncbi.nlm.nih.gov/32616673/.

[111] According to early media reports, doctors in South Korea initially suspected that positive PCR tests in previously recovered patients indicated re-infections, but later those were determined to be false positives due to testing errors. *See* http://www.koreaherald.com/view.php?ud=20200429000724; https://thehill.com/changing-america/well-being/medical-advances/495646-no-evidence-of-coronavirus-reinfections-south. The hunt for re-infections has been a global effort and out of the over 42 million people that have tested positive for SARS-CoV-2 worldwide (*see* https://covid19.who.int/ showing 42,055,863 confirmed cases as of October 24, 2020) – and the likely hundreds of millions more that have had it but have not been tested – there are only five cases found in the entire world where scientists think evidence may point to a possibility of a re-infection (that is 5/42,000,000 = 0.0000119% of all currently documented cases): one in Asia (*see* https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1275/5897019), two in Europe (*see* https://academic.oup.com/cid/advance-article/doi/10.1093/

Those individuals who have already been infected have developed the best possible immunity to the virus and there is no evidence they are at risk of becoming re-infected and transmitting the virus. Nor is there evidence that a vaccine will confer superior immunity as compared to that conferred by natural infection. The NYSBA report does not account for this reality and it should be taken into account with regard to any COVID-19 vaccine recommendation.

VI. Children and COVID-19 Vaccines

In addition to a lower herd immunity threshold, another thing that has become exceedingly clear is that while children are capable of carrying SARS-CoV-2, it has not posed a significant threat to them. Children do not become sick as often as adults and most who do get SARS-CoV-2 have mild or no symptoms.[112]

Further, the CDC explains:

> Scientific studies suggest that COVID-19 transmission among children in schools may be low. International studies that have assessed how readily COVID-19 spreads in schools also reveal low rates of transmission when community transmission is low. Based on current data, the rate of infection among younger school children, and from students to teachers, has been low, especially if proper precautions are followed. There have also been few reports of children being the primary source of COVID-19 transmission among family members. This is consistent with data from both virus and antibody testing, suggesting that children are not the primary drivers of COVID-19 spread in schools or in the community.[113]

This is all great news and should not be ignored. Historically, the burden of herd immunity has been placed on the shoulders of school-age children via school mandates. However, members of the Vaccines and Related Biological Products Advisory Committee, at their recent October 22, 2020 meeting, rightly expressed concern about clinical trials moving to include children, especially given their exceptionally low risk related to SARS-CoV-2. They recognized that the benefit/risk

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cid/ciaa1330/5901661; https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1538/5920950), one in South America (*see* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3686174), and one in North America (*see* https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30764-7).

But even for these extremely rare cases of probable re-infection, the science is not settled. For example, the authors of the study that analyzed a U.S. case admit that "[i]t is possible that we have reported a case of continuous infection" (*id*.) rather than re-infection. Furthermore, even in the infinitesimally small number of probable re-infection cases, there was no evidence obtained that those individuals could or did transmit the virus.

[112] *See* https://covid.cdc.gov/covid-data-tracker/#demographics (Children ages 0-4 account for only 1.7% of all COVID-19 infections and those ages 5-17 account for only 7.2%. Likewise, children account for only 0%-0.3% of all COVID-19 deaths, with 101 deaths throughout the pandemic. This is significantly lower than even regular flu season deaths wherein child deaths have reached as high as 187 in one season).

[113] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/reopening-schools.html.

analysis concerning a vaccine for SARS-CoV-2 for children differs greatly from the same analysis concerning a vaccine for adults. Where a vaccine's benefits may outweigh its risk for a portion of the population, that difference should be taken into consideration when deciding whether to mandate the vaccine.

VII. Lack of Actual Exemptions to Vaccinations in New York State

If the NYSBA is going to recommend mandating a COVID-19 vaccine, it should assure that groups such as children are not included in the recommendation, and that there are robust exemptions for adults to which the recommendation applies. In particular, providing for a medical exemption that is left to an individual's doctor to decide, not government bureaucrats.

For example, at present, it is nearly impossible to obtain a medical exemption to vaccination to attend school in New York irrespective of how firm the medical opinion of a child's doctor that the child may be seriously injured by continued vaccination. This is because to obtain a medical exemption a doctor's opinion is not sufficient; that opinion must directly align with either (i) the CDC's Advisory Committee on Immunization Practices ("**ACIP**") guidelines for contraindications and precautions to childhood vaccinations ("**ACIP Guidelines**") or (ii) some other nationally recognized evidence-based standard of care which the NYSDOH has effectively interpreted to mean ACIP Guidelines, therefore crippling the ability for medically fragile children to obtain a medical exemption.[114] Proffered medical exemptions are denied almost consistently by school nurses, non-treating school physicians, school boards, and school administrators.

This means that in the event a COVID-19 vaccine is mandated for children in New York State in order to attend daycare or school, there will be effectively no way for a parent and doctor to exempt a child from receiving such a vaccine when they believe that the risk/reward analysis for that particular child weighs against him/her receiving the vaccine. This further erodes the doctor-patient relationship, parental choice, and numerous other rights long enjoyed by Americans.

* * *

If the clinical trials of COVID-19 Vaccines are substandard and if those overseeing the trials and profiting from the vaccines are conflicted, and if the manufacturers are not held liable for these vaccines, then the choice as to whether to take these vaccines must be left to an individual and his/her doctor – there cannot be a universal mandate backed by the force of the state in the face of such concerning realities.

[114] https://www.health.ny.gov/professionals/doctors/conduct/docs/medical_exemptions_guidlines.pdf.

ICAN remains dedicated to ensuring that the public has accurate, up-to-date, unbiased information regarding the COVID-19 Vaccines. Each of the above concerns, individually and together, warrants your further review so that you can act accordingly, thereby ensuring the safety of all American citizens, including those who are likely to be mandated to receive one or more of the COVID-19 Vaccines that the FDA licenses. We would welcome providing any additional information or meeting with you to discuss any of the foregoing information.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
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