UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

and

PATRICK AND STEPHANIE DE GARAY,

Plaintiffs,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:22-cv-915-P

BRIEF IN SUPPORT OF TIMELY PRODUCTION SCHEDULE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

INTRODUCTION

Plaintiffs, PHMPT and Patrick and Stephanie de Garay, respectfully come before this Court to seek a production schedule for the documents submitted by Pfizer to the FDA to license its Covid-19 vaccine for 12- to 15-year-old children ("**Pfizer 12-15 data**") and for the documents submitted by Moderna to the Food and Drug Administration ("**FDA**") to license its Covid-19 vaccine for adults ("**Moderna data**").

PHMPT 1 Related Proceeding

The Court dealt with a similar request seeking the documents the FDA relied upon to license Pfizer's Covid-19 vaccine for those 16 and older ("**Pfizer 16+ data**") in a related action, *PHMPT v. FDA* (4:21-cv-01058-P) ("**PHMPT 1**"). After extensive briefing and oral argument, and patiently listening to both sides, the Court reasoned that the FDA must produce the expected 450,000 pages at the rate of 55,000 pages per month starting on or before March 1, 2022. (PHMPT 1, ECF 35.) The FDA desired to move out the start date, and the parties agreed, in relevant part, on the following schedule, again expecting that production of the approximately 450,000 pages would be completed in 2022: "The FDA will produce 80,000 pages on or before May 2, June 1, and July 1, 2022; 70,000 pages on or before August 1, 2022; and then 55,000 pages on or before the first business day of each month thereafter." (PHMPT 1, ECF 56.)

Current Requests and Exigent Need for Same

As with the Pfizer 16+ data, PHMPT also wants to make public the Moderna data and the Pfizer 12-15 data. There is an acute need for the Pfizer 12-15 data to be made public because the other Plaintiffs in this action, the de Garays, have a daughter who was just one of 1,131 children who received the vaccine in the clinical trial for Pfizer's Covid-19 vaccine for this age group. Directly after her second shot, she was rushed to the emergency room and eventually ended up in

a wheelchair with a feeding tube, which remains her current condition. Despite her serious and ongoing adverse reaction, Pfizer reported her serious harm to the FDA as mere "functional abdominal pain." The undersigned sent the FDA the child's medical records and repeatedly tried to notify it about this misrepresentation, including in three additional letters. When the FDA finally responded 128 days later, on February 26, 2022, it merely suggested that the de Garays file a VAERS report (which, of course, they had already done). In addition to this very specific and serious safety issue, there are also clear efficacy issues with this product that independent scientists need to review.

The Moderna trial has similar issues concerning the safety and efficacy of the product that independent scientists need to be able to review. As detailed below, these include serious efficacy issues such that recent studies, including a 50,000 person Cleveland Clinic study, have found that those receiving this vaccine are, in fact, more likely to have Covid-19 than those that do not receive this vaccine; and that the more doses received, the more likely one is to have Covid-19.

In PHMPT 1, Plaintiff's members have been chomping at the bit to get the full production because, as repeatedly explained in that action, until they have all the documents, they cannot conduct a proper analysis. For example, there appear to be 20 deaths among those getting the Covid-19 vaccine and 14 among those getting the placebo, but an analysis of this data cannot be properly performed until all the documents in PHMPT 1 are produced. There were also 3,410 total cases of "suspected but unconfirmed Covid-19" in Pfizer's trial which were not counted as part of the efficacy results because Pfizer decided to exclude them. Knowing the exact number of such individuals, and how many were in the placebo and how many in the vaccine group, is critical for an accurate calculation of the actual efficacy of Pfizer's Covid-19 vaccine in its clinical trial for

those 16 and older. None of this, like many other analyses, can be performed until all the data is produced.

Given these exigencies and seeing firsthand just how critical having *all* the data is, Plaintiffs sought expedited processing for the Pfizer 12-15 data and the Moderna data. The FDA denied this request and denied their appeal of the denial. This action therefore ensued.

In an effort to comport with the guidance from the Court in PHMPT 1, Plaintiffs' complaint, filed on October 11, 2022, requested that the FDA be required to continue producing, at the rate of 55,000 pages per month, the documents requested herein upon completion of the production in PHMPT 1, which at that time PHMPT expected to occur in 2022. What Plaintiffs did not realize is that PHMPT was misled into believing there were only around 450,000 pages to produce in PHMPT 1. It is now clear that was not the case because the FDA has already produced 765,479 pages, and there is, apparently, no end in sight.

Reflecting the likely volume of the responsive documents to be produced in PHMPT 1, the FDA has now advised Plaintiffs that there are around 4 million pages submitted by Moderna to license its product (in addition to other responsive documents in the product file). PHMPT has written a letter to the FDA in PHMPT 1 advising that it believes the FDA was not candid with the plaintiff or the Court in that matter. The FDA's only substantive response to date has been that the "FDA is working diligently to make those estimates [estimated remaining page count] as precisely as possible" and will not provide even a ballpark estimate on when completion of production in PHMPT 1 will occur, despite numerous requests.

Requested Production Schedule

Given the foregoing, Plaintiffs respectfully seek a production schedule in this matter independent of the production schedule in PHMPT 1. In that matter, the FDA claimed its resources,

despite billions of dollars in taxpayer funds, limited it to producing at the rate of 500 pages per month. The Court, however, explained that "excessive delay by the agency in its response is often tantamount to denial" and that a "production rate [of 55,000 pages per month] … appropriately balances the need for unprecedented urgency in processing this request with the FDA's concerns regarding the burdens of production."

This appropriate balancing presumably assumed there were approximately 450,000 pages which would have resulted in the completion of the production in 2022. This careful balancing was, however, based on the misleading understanding there were around 450,000 pages. It is therefore respectfully submitted that the FDA should not be permitted to now seek to delay production of the Pfizer 12-15 data and the Moderna data in order to complete production of the Pfizer 16+ data.

It is also clear the FDA can produce far more than 55,000 per month, having produced in PHMPT 1:

- 90,702 pages in May 2022,
- 90,640 pages in June 2022,
- 90,877 pages in July 2022,
- 88,656 pages in August 2022, and
- 88,142 pages in September 2022.

Until this month, the FDA had continued to produce a minimum of 55,000 pages per month, and the same types of documents have been produced during the months when approximately 90,000 pages were produced and months when 55,000 pages have been produced. This reflects that the FDA can produce at least 35,000 additional pages per month and, respectfully, likely hundreds of thousands of more pages per month if the FDA applied just .001% of the taxpayer dollars it receives.

FDA has advised that the Pfizer 12-15 data is 497,289 pages in the Biologic License Application (not counting other responsive documents within the product file). Assuming this number is accurate, it would take approximately 9 months to produce at the rate of 55,000 pages per month. Plaintiffs respectfully request that the FDA be ordered to produce all of the Pfizer 12-15 data at the rate of at least 55,000 pages per month, with the final production of any remaining documents to occur on October 15, 2023.

Again seeking to remain within the range of the Court's prior guidance, Plaintiffs also request that, at minimum, the FDA be required to produce all of the Moderna data within 18 months of completion of the Pfizer 12-15 data at the rate of at least 55,000 pages per month with the final production of any remaining documents to occur on April 15, 2025. The Plaintiffs, however, respectfully submit that a shorter production schedule would be more appropriate, especially considering that the Moderna Covid-19 vaccine was designed, developed, manufactured, and purchased using taxpayer funds, but make the foregoing production schedule proposal in an attempt to remain in accord with the Court's prior guidance.

FACTS

I. PLAINTIFFS PHMPT AND THE DE GARAYS

PHMPT has approximately 5,865 members, mostly comprised of medical and public health professionals, including professors and researchers in medical-related disciplines from Yale School of Public Health, UCLA David Geffen School of Medicine, University of Maryland School of Pharmacy, Warren Alpert Medical School of Brown University, Oregon Health & Science University, UC San Francisco, David Geffen School of Medicine at UCLA, University of

Leicester, University of Southern Denmark, University of Sydney, University of Oxford, University of Toronto, and University of Auckland, as well as other universities and journalists.[1]

Patrick and Stephanie de Garay are the parents of now 14-year-old M.D., who has suffered and continues to suffer severe adverse events following vaccination in Pfizer's clinical trial for 12- to 15-year-olds. M.D. was one of only 1,131 participants in Pfizer's clinical trials for the 12 to 15-year-olds who received a Covid-19 vaccine.[2] Within 24 hours of receiving the second dose of the vaccine during the clinical trial on January 20, 2021, M.D., at 12 years old, experienced a serious adverse reaction to the vaccine, including severe pain throughout her body and the feeling that her "heart was being ripped out through her neck," and she presented to the emergency room.[3] M.D. was subsequently admitted to the hospital and later discharged with the diagnosis that her symptoms resulted from an adverse reaction to the vaccine.[4] M.D.'s health continued to rapidly decline and, despite the de Garays' thorough documentation, reporting, and outreach regarding their daughter's sudden onset symptoms – which ultimately necessitated her continued use of a feeding tube and wheelchair – the de Garays received no attention from Pfizer or the FDA.[5] In Pfizer's data presented to the FDA in its application for an EUA, M.D.'s severe, systemic, and ongoing adverse reaction to the Pfizer 12-15 vaccine was categorized as "functional abdominal pain."[6] FDA granted emergency use authorization of Pfizer's vaccine for 12 to 15-year-olds on May 10, 2021.

---

[1] *See* https://phmpt.org/.

[2] *See* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use; *see also* Patrick de Garay's Declaration (**Exhibit 7** at pages 9-10.)

[3] https://thehighwire.com/videos/rigged-maddies-story/ (see video at 6:44-8:20).

[4] *Id*. *See also* https://www.sirillp.com/wp-content/uploads/2021/10/1-21-2021-My-Health-Summary-pgs-1027-to-1034_Redacted-b3f4451617070003bed8aaff8a47d98a.pdf.

[5] *See generally id.*

[6] *Id*. at 1:04:40. *See also* https://www.fda.gov/media/148542/download at 30.

Notwithstanding the de Garays' reporting of their daughter's wide range of severe symptoms, Pfizer's inaccurate and misleading characterization thereof, the inadequate assessment of potential causality of M.D.'s injuries from the vaccine, and the safety alarms that this should have been ringing, FDA granted the vaccine EUA on May 10, 2021 and – after the undersigned wrote to FDA about M.D. on October 22, 2021, October 25, 2021, January 3, 2022, February 7, 2022, and March 8, 2022[7] – the agency subsequently licensed the use of the Pfizer 12-15 Vaccine on July 8, 2022.[8]

The FDA also was invited to the November 2021 round table held by Senator Ron Johnson with regard to those injured by Covid-19 vaccines – at which Stephanie de Garay spoke, and M.D. was present – but did not attend.[9] There has also been widespread media coverage of M.D.'s case, but, nonetheless the FDA has failed to reach to the de Garays.[10]

---

[7] *See* https://www.sirillp.com/wp-content/uploads/2023/03/3-08-2022-Ltr-to-Dr.-Paul-Richards-FDA-re-Maddie-de-Garay-608d98239f37f6f035190541103e5dc5.pdf.

[8] *See* https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022.

[9] *See* https://rumble.com/vokrf7-sen.-johnson-expert-panel-on-federal-vaccine-mandates.html at 22:25 (November 2, 2021: Appearance on Senator Ron Johnson's Expert Panel on Federal Vaccine Mandates.); Senator Johnson also held a second roundtable concerning the Covid-19 vaccines to which FDA was also invited and did not attend. *See* https://www.ronjohnson.senate.gov/2022/12/sen-ron-johnson-hears-from-experts-and-medical-professionals-on-covid-19-vaccine-efficacy-and-safety.

[10] *See* https://youtu.be/lAeVLdMnerQ?t=1885. (June 28, 2021: Appearance on Senator Ron Johnson's press conference with individuals who suffered adverse reactions to COVID-19 vaccines); *see also* https://thefederalist.com/2021/06/29/twitter-censors-video-of-mother-describing-daughters-covid-19-vaccine-side-effects/ (June 29, 2021: Federalist Article: "Twitter Censors Video of Mother Describing Daughter's COVID-19 Vaccine Side Effects"); https://www.foxnews.com/transcript/tucker-people-in-charge-create-disaster-after-disaster at 12:00 (July 1, 2021: Coverage of testimony at Senator Ron Johnson press conference by Tucker Carlson Tonight.); https://video.foxnews.com/v/6262045756001#sp=show-clips (July 2, 2021: Appearance on Tucker Carlson Tonight); https://rumble.com/vsgwe2-joe-rogan-on-maddie-de-garay-and-suppression-of-vaccine-adverse-events..html (January 12, 2022: Discussion of de Garays by podcast host Joe Rogan on the Joe Rogan Experience.); https://thehighwire.com/videos/rigged-maddies-story/ (August 13, 2022: Appearance on The HighWire, "Rigged: Maddie's Story.").

II. FDA LICENSURE OF MODERNA AND PFIZER 12-15 COVID-19 VACCINE

On January 31, 2022, the FDA approved the Moderna Covid-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older.[11] FDA asserts that "Spikevax meets the FDA's high standard for safety, effectiveness, and manufacturing quality required of any vaccine approved for use in the United States."[12]

On July 8, 2022, FDA approved the Pfizer-BioNTech Covid-19 Vaccine, marketed as Comirnaty, for individuals 12 through 15 years of age (the "**Pfizer 12-15 Vaccine**").[13] FDA asserts its "approval follows a rigorous analysis and evaluation of the safety and effectiveness data conducted by FDA."[14]

Plaintiffs seek the release of the records relied upon by the FDA to license these products. The importance of releasing this information to the public is explicitly recognized under federal regulation, which provides: "After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . ."[15]

Hence, upon licensure for the Pfizer 12-15 Vaccine and Moderna Vaccine (the "**Covid-19 Vaccines**"), PHMPT issued two requests to FDA pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**") for "[a]ll data and information for [the COVID-19 Vaccines]

---

[11] *See* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[12] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[13] *See* https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022.

[14] https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022.

[15] 21 C.F.R. § 601.51(e).

enumerated in 21 C.F.R. § 601.51(e)[16] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System."[17] A near identical request for the Pfizer 12-15 Vaccine was later submitted to FDA by Patrick and Stephanie de Garay.[18]

III. SERIOUS PUBLIC CONCERNS RAISED REGARDING THE FDA'S DECISION

Despite FDA's assertions, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large media platforms have publicly raised questions regarding the sufficiency of the data, the adequacy of the review, and the appropriateness of the analyses relied upon by FDA to license the Covid-19 Vaccines. The de Garays, based on their personal experience with the Pfizer product, similarly question how their daughter's case was handled and the evidence regarding the thoroughness and reliability of the larger clinical trial.

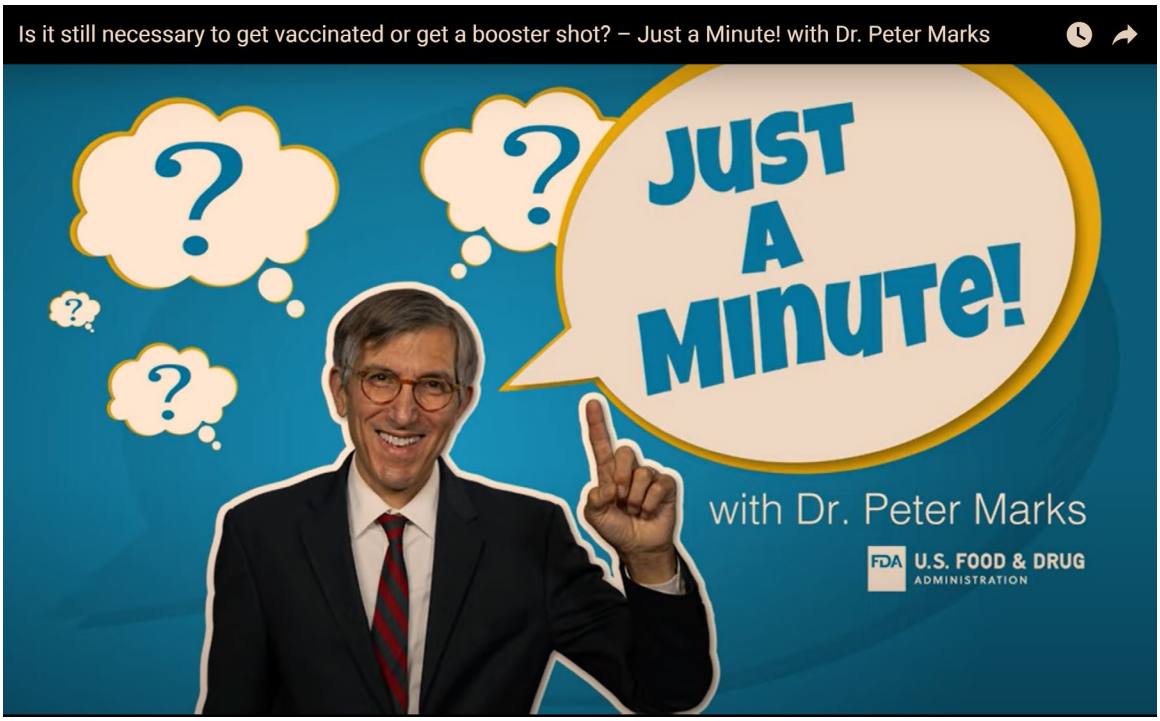
Independent review is critically needed because the FDA was already promoting these products prior to their licensure, potentially biasing their decision-making process. For example, Dr. Peter Marks, the head of the FDA's division that decides on licensure of these products, put out promotional videos encouraging the uptake for unlicensed uses of these products:

---

[16] 21 C.F.R. § 601.51(e) provides that, after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[17] For the avoidance of doubt, the FOIA Request includes, but is not limited to, all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for [the COVID-19 Vaccines], enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

[18] https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair; *see also* https://thehighwire.com/videos/rigged-maddies-story/.



While Dr. Marks was making promotional videos,[19] he also received letters about the serious injuries M.D. sustained in the Pfizer 12-15 clinical trial that he ignored.

There were also numerous prestigious journals that published articles calling into question many aspects of the decision to authorize these products, which apparently were not considered when the FDA licensed them. A petition about these issues was recently filed with the FDA by 9 highly credentialed and world-renown scientists, two of whom are PHMPT members, which requested the following actions by the FDA:

> 1. Add language clarifying that phase III trials were not designed to determine and failed to provide substantial evidence of vaccine efficacy against SARS-CoV-2 transmission or death.

[19] *See, e.g.,* https://www.youtube.com/watch?v=IJNc_DJ1DyE (*Do the current COVID-19 vaccines work?*, January 27, 2022); https://www.youtube.com/watch?v=k9ekkC3fhqo (*Risks of not getting my child vaccinated against COVID*-19, February 10, 2022); https://www.youtube.com/watch?v=YgPj5MoD3hY (*When might we have vaccines for our youngest children?*, February 25, 2022); https://www.youtube.com/watch?v=EGIhEcGZaQg (*Is it still necessary to get vaccinated or get a booster shot?*, April 4, 2022); https://www.youtube.com/watch?v=bf7zBKszkJo (*Should 12-through 17-year-olds receive a COVID-19 booster?*, March 24, 2022). Each of these videos predates FDA approval of Pfizer's 12-15 vaccine and features Dr. Marks promoting the Covid-19 vaccines.

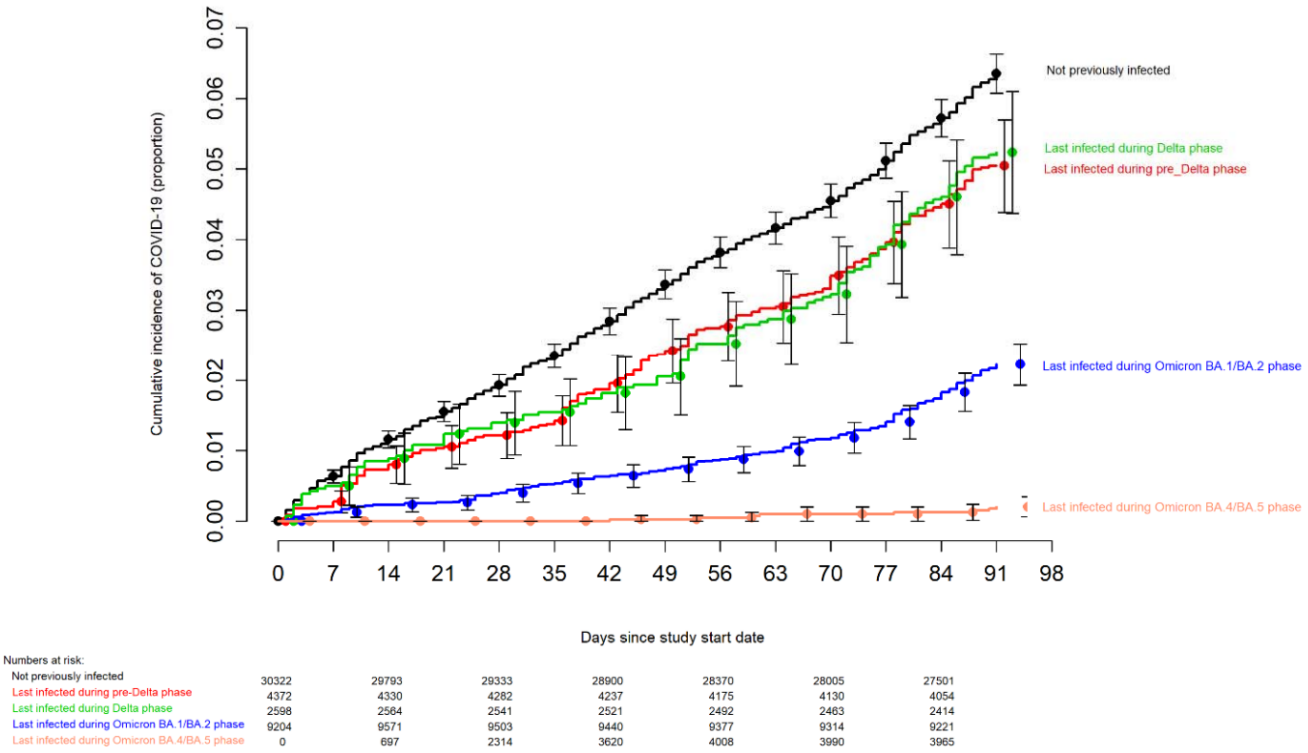
2. Add language clarifying that the immunobridging surrogate endpoint used in multiple authorized indications has not been validated to predict clinical efficacy.
3. Add safety and efficacy results data from manufacturer randomized trials of current bivalent boosters that reported results after EUA was granted.
4. Add a clear statement that FDA authorized a new Pfizer vaccine formulation containing Tris buffer without requiring clinical studies to evaluate efficacy, safety or bioequivalence to the formulation containing phosphate buffer.
5. Add a clear statement disclosing that a Pfizer phase III randomized trial in pregnant women (NCT04754594) was completed as of July 2022 but there have been no results reported.
6. Add a clear statement that Pfizer vaccine efficacy wanes after 2 months following dose 2 according to the Pfizer phase III randomized trial.
7. The following adverse event types should be added to the Adverse Reactions section of labeling:
   a. multisystem inflammatory syndrome (MIS) in children;
   b. pulmonary embolism;
   c. sudden cardiac death;
   d. neuropathic and autonomic disorders.
8. The following reproductive health and lactation related adverse event types should be added to the Adverse Reactions section of labeling:
   a. decreased sperm concentration;
   b. heavy menstrual bleeding;
   c. detection of vaccine mRNA in breastmilk.
9. Add frequency data for clinical and subclinical myocarditis.
10. Labeling should present trial results on serious adverse events in tables with statistics, as is done for non-serious adverse events.
11. Petitioner also requests the FDA create a Medication Guide and communicate these labeling changes via a Dear Health Care Provider (DHCP) letter.[20]

There are far more issues and questions that can likely be answered if the data requested in PHMPT 1 and herein were made public. For example, a paper published on June 23, 2022 and updated on September 9, 2022 titled *Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials*, states: "These study limitations all stem from the fact that the raw data from

[20] https://www.regulations.gov/document/FDA-2023-P-0360-0001.

COVID-19 vaccine clinical trials are not publicly available. Given the global public health implications, **there is an urgency to make all COVID-19 trial data public, particularly regarding serious adverse events, without any further delay**."[21]

The urgency to publicize all this data is becoming more acute with each passing day. For example, a recent Cleveland Clinic study of over 50,000 individuals found that the more doses of Covid-19 vaccine received, the greater the chances of getting Covid-19:[22]



Numerous other recent papers have presented data that have called into serious question the efficacy of these vaccines, including data that reflect issues that should have been seen during

[21] *Fraiman, J., et al., Serious adverse events of special interest following mRNA vaccination in randomized trials*, SSRN (June 23, 2022) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239 (emphasis added).

[22] *See* Nabin K. Shrestha, *et al., Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine*, Medrxiv (Dec. 19, 2022), https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf?utm_source=substack&utm_medium=email.

the clinical trial if it had been conducted properly and had the results been fully reported to the FDA:

a. An article in the New England Journal of Medicine discusses a study that included 887,193 children (273,157 vaccinated children) and showed that children who had Covid-19 and were subsequently vaccinated were much more likely to get reinfected than their peers who also had Covid-19 and were not vaccinated.[23]

b. Data from the Dutch government evaluating mRNA vaccines found that "in the period from March 15 to June 28, 2022, there was hardly any visible protective effect of the COVID-19 basic vaccination series against hospital and ICU-intake." In fact, when researchers stratified the risks of hospitalization and intensive care by time from the date of vaccination and by age, it was demonstrated that the risks increase over time.[24]

c. A study among adolescents in Brazil and Scotland analyzed vaccine effectiveness of two doses of Pfizer's vaccine against symptomatic and severe Covid-19. The study found waning vaccine protection against symptomatic Covid-19 from 27 days after the second dose.[25]

d. A study published in the Lancet looking at effectiveness of Pfizer's vaccine in children in Italy states: "Our estimates of the effectiveness of full vaccination

---

[23] *See Lin, Dan-yu, et al., Letter to the Editor: Effects of Vaccination and Previous Infection on Omicron Infections in Children,* NEJM (Sept. 22, 2022) https://www.nejm.org/doi/full/10.1056/NEJMc2209371?query=featured_home.

[24] *See* https://www.rivm.nl/covid-19-vaccinatie/bescherming-coronavaccins-tegen-ziekenhuisopname/booster-en-herhaalprik-bij-ouderen-nodig-om-bescherming-op-peil-te-brengen (Dutch version). https://www.rivm.nl/en/covid-19-vaccination/vaccine-effectiveness-in-preventing-hospital-admissions/covid-19-booster-jab-and-repeat-vaccination-needed-for-older-people-to-restore-protection (English version).

[25] *See* Florentino, P.T. *et al., Vaccine effectiveness of two-dose BNT162b2 against symptomatic and severe COVID-19 among adolescents in Brazil and Scotland over time: a test-negative case-control study,* Lancet Infect Dis. (Aug. 8, 2022) https://pubmed.ncbi.nlm.nih.gov/35952702/.

against SARS-CoV-2 infection are significantly lower than those reported in the clinical trial that led to the approval of BNT162b2 in children (90.7% in the approval trial *vs* 29.4% in our study)." The study also states, "our estimates of vaccine effectiveness against infection coincide with the estimate reported in the USA in a previous study" and that "this decline could be due to immunity waning, as described in the adult population vaccinated with mRNA vaccines."[26]

e. A study printed in *JAMA*, conducted from December 2021 to February 2022 during Omicron variant predominance and included 121,952 tests from sites across the United States, estimated vaccine effectiveness against symptomatic infection among adolescents 12 to 15 years of age at 16.6% at two months after two doses. The study concluded: "Among children and adolescents, estimated VE for 2 doses of [Pfizer's vaccine] was modest and decreased rapidly."[27]

Likewise, numerous recent papers have presented data of serious safety issues with these vaccines, including data that reflects issues that should have been seen during the clinical trial if it had been conducted properly and the results fully reported to the FDA, including immune, neurological, and circulatory system disorders. For example, a recent peer-reviewed study looking at close to 300,000 people in California finds that Covid-19 vaccines are linked to a 20% rise in new diagnoses for at least three months post-vaccination. More specifically, adults have sharply higher risks of being diagnosed with heart, skin, and psychiatric conditions for at least 90 days

[26] *See* Sacco, C., et al., *Effectiveness of BNT162b2 vaccine against SARS-CoV-2 infection and severe COVID-19 in children aged 5-11 years in Italy; a retrospective analysis of January-April, 2022,* The Lancet (July 9, 2022) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01185-0/fulltext.

[27] *See* Fleming-Dutra, K., *et al., Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-C0V-2 Infection in Children and Adolescents During Omicron Predominance,* AMA JAMA (June 14, 2022) https://pubmed.ncbi.nlm.nih.gov/35560036/.

after they receive Covid-19 shots.[28] Additionally, the following is a list of studies on the adverse effects on the heart and circulatory system in children from the Covid-19 vaccine:

a. A recent study in the American Heart Association journal, conducted between December 2020 and December 2021, acknowledged that deaths had resulted from myocarditis post-vaccination, identifying 345 people in England who had died of myocarditis after receiving a Covid-19 vaccine.[29]

b. Another study in Tropical Medicine and Infectious Disease of 301 adolescents found that 54 patients, or 17.94%, had abnormal electrocardiograms after vaccination with Pfizer's Covid-19 vaccine, resulting in one case of myopericarditis, four cases of subclinical myocarditis, and two cases of pericarditis.[30]

c. A Kaiser Permanente study determined that the rate of myocarditis used by federal health authorities was incorrect and that the actual rate was nearly double, at 1 in 4,800 children vaccinated, observing, "The true incidence of myopericarditis is markedly higher than the incidence reported to US advisory committees," as the study had identified "approximately twice as many cases of myopericarditis following COVID-19 mRNA vaccination." [31]

---

[28] Kwan, A. et al., *Apparent risks of postural orthostatic tachycardia syndrome diagnoses after COVID-19 vaccination and SARS-Cov-2 infection*, (Dec. 12, 2022), https://www.nature.com/articles/s44161-022-00177-8?utm_source=substack&utm_medium=email#author-information.

[29] Patone, M., *et al*., *Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex*, Circulation (Aug. 22, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439633/.

[30] Mansanguan, S.*, et al*., *Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents*, Tropical Med. & Infec. Dis. (Aug. 19, 2022), https://www.mdpi.com/2414-6366/7/8/196/htm.

[31] Shariff, K.., *et al.*, *Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods*, MedRxiv (Dec. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1.full.pdf.

d. A study from the Norwegian Institute of Public Health involving 23.1 million Scandinavians ages 12 and up found that the risk of myocarditis after mRNA vaccines was highest in males aged 16 to 24 after the second dose.[32]

e. An analysis of 42 million people ages 13 and older by Oxford researchers found higher rates of vaccine-induced myocarditis than Covid-19-induced myocarditis in males ages 16 to 39 after second and third doses of Pfizer's Covid-19 vaccine and after first and second doses of Moderna's Covid-19 vaccine.[33]

There is also an urgent need for full transparency regarding these products because Americans are still being mandated or otherwise pressured to take this product by the federal government,[34] local governments,[35] public and private employers,[36] universities,[37] schools,[38] and

---

[32] Karlstad, O., *et al.*, *SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents*, JAMA Cardiology (Apr. 20, 2022), https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253.

[33] Patone, M., *et al.*, *Risk of Myocarditis Following Sequential COVID-19 Vaccinations by Age and Sex*, MedRxiv (Dec; 25, 2021), https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf+html.

[34] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1; https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c; https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF.

[35] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html; https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page; https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html?guccounter=1.

[36] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html; https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/; https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220; https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/; https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html; https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/; https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates/; https://www.cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees.

[37] *See e.g.*, https://blockclubchicago.org/2022/07/18/will-your-college-still-require-covid-vaccinations-now-that-the-state-dropped-its-mandate/; https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916; https://www.colorado.edu/covid-19-updates/covid-19-vaccination; https://uhs.berkeley.edu/requirements/covid19.

[38] *See, e.g.*, https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087; https://www.4j.lane.edu/coronavirus/healthsafety/ (school staff and volunteers must get Covid-19 vaccine); https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students; https://patch.com/massachusetts/salem/salem-school-committee-approves-

various other institutions, all at the direct or indirect recommendation or encouragement of the Federal Government, all of which is premised on the FDA's conclusion these products are safe and effective.[39]

Furthermore, now that FDA has approved the Pfizer 12-15 Vaccine, there are indications that states and school districts will begin mandating these vaccines for children to attend public school.[40] Washington, D.C., has already announced a mandate for students ages 12 and older.[41]

IV. THE FOIA REQUESTS

PHMPT submitted a FOIA request on February 23, 2022, seeking the following documents to be produced on an expedited basis pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II):

> All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[42] with the exception of publicly available reports

---

vaccine-mandate-sports-band; https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/; https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html; https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/.

[39] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/; https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/; https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html; https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers; https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx; https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html; https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees; https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/.

[40] https://www.gov.ca.gov/2021/10/01/california-becomes-first-state-in-nation-to-announce-covid-19-vaccine-requirements-for-schools/; *see also* https://www.latimes.com/california/story/2022-01-24/new-vaccine-legislation-california-schoolchildren-mandate.

[41] *See* https://osse.dc.gov/page/district-columbia-immunization-attendance-policy ("Beginning in the 2023-24 school year, the COVID-19 vaccine is required for school enrollment and attendance in the District of Columbia for all students who are of an age for which there is a COVID-19 vaccination fully approved by the US Food and Drug Administration (FDA)").

[42] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

> on the Vaccine Adverse Events Reporting System.[43]

(Dkt. No. 1 at 17) On March 7, 2022, FDA denied PHMPT's request for expedited processing ("**PHMPT's Denial Letter**" or "**Denial Letters**") and assigned the request FOIA Control # 2022-1614. In PHMPT's Denial Letter, FDA stated, in relevant part:

> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(*Id*. at 17-18.) On June 1, 2022, PHMPT submitted an appeal challenging FDA's decision to deny PHMPT's requests for expedited processing. (*Id*. at 18) FDA acknowledged PHMPT's appeal on June 1, 2022, assigned it appeal file 20-0076AA, and declared that the appeal fell under "unusual circumstances" pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA. (Dkt. No. 1 at 18.) Given the "unusual circumstances" claimed by FDA, it was required to make a determination with respect to PHMPT's appeal for expedited processing by July 15, 2022. As of the date of this filing, FDA has not made a determination.

PHMPT also submitted the following FOIA request to FDA on August 8, 2022 and sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II):

[43] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

> All data and information for the Pfizer 12-15 Vaccine enumerated in 21 C.F.R. § 601.51(e)[44] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[45]
>
> This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (previously made on behalf of PHMPT) and is meant to capture all data and information within the biological product file that concerns the authorization and approval of Comirnaty for use in 12-15-year-olds.

(Dkt. No. 1 at 18.) On August 15, 2022, FDA denied PHMPT's request for expedited processing ("**PHMPT's Denial Letter**" or "**Denial Letters**"). In PHMPT's Denial Letter, FDA stated, in relevant part:

> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(*Id*. at 19)

The de Garays also submitted a request to FDA on August 22, 2022 for the data relied upon to license the Pfizer 12-15 Vaccine and sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II). (Dkt. No. 1 at 19-20) On August 29, 2022, FDA denied the de Garays' request for expedited processing ("**de Garays' Denial Letter**" or "**Denial Letters**") and assigned the request FOIA Control # 2022-6129. In the de Garays' Denial Letter, FDA stated in relevant part:

---

[44] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[45] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(*Id*. at 20.)

ARGUMENT

The urgency to inform the public concerning the data and information underlying a licensed vaccine is reflected in the Code of Federal Regulations, which expressly provides that "[a]fter a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information . . . ."[46] Therefore, FDA's own regulations expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure."[47] FDA's regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of this request.

Moreover, FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor, which must be sufficient to demonstrate the product is both "safe"

[46] 21 C.F.R. § 601.51(e) (emphasis added).

[47] *Id*.

and "effective."[48] To assure FDA's commitment to transparency[49] and to promote the public's and the medical and scientific communities' confidence in the conclusions reached by FDA, it is not surprising that 21 C.F.R. § 601.51(e) requires FDA to immediately disclose all safety and effectiveness data after a product is licensed, absent any extraordinary circumstances. This is the same information that would be responsive to Plaintiffs' requests.

Beyond the FDA's own regulations, which admit the urgent need for transparency and disclosure of the requested information, there are two additional reasons that warrant a reasonable and timely production of responsive documents.

First, as explained above,[50] there is an ongoing, national public debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the Covid-19 Vaccines.

Although public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large media platforms have declared that the data and information underlying the licensure of the Covid-19 Vaccines are more than sufficient for licensure, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Covid-19 Vaccines, including a number of the scientists and journalists that are members of PHMPT.

---

[48] 21 C.F.R. § 601.2 (a). FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download; *see also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved; https://www.fda.gov/about-fda/what-we-do.

[49] https://www.fda.gov/about-fda/transparency.

[50] *See, e.g.*, *supra* ¶¶ 36-45.

The public debate is unlikely to be settled without full disclosure of the data and information underlying the FDA's conclusion that the Covid-19 Vaccines are "safe and effective."

Secondly, there is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Covid-19 Vaccines because, over the objections of many, this product has been, and continues to be mandated to individuals across the country by the federal government, local governments, public and private employers, universities, schools, and various other institutions.[51]

Regarding the Pfizer 12-15 Vaccine, after its FDA approval, policymakers are reviewing the available information to determine if Covid-19 vaccine requirements are appropriate for students for the 2023-2024 school year and beyond.[52]

Having multiple trusted independent authorities review the safety and effectiveness data sought in these FOIA requests will only assist the public and private institutions in evaluating vaccine decisions and policies.

During a time when Covid-19 vaccine mandates are being implemented over the objection of those who have questions about the data and information supporting the safety and efficacy of the Covid-19 Vaccines, and individuals with these questions are being expelled from employment, school, and other critical parts of civil society, the public has an urgent and immediate need to have access to this data.

It is crucial that the American public be granted the transparency necessary – and on the timeline necessary – to review and assess the government's justifications for its actions. The declared emergency of Covid-19 led to numerous government actions that greatly affected the

[51] *See, e.g.*, *supra* ¶¶46-47.

[52] *See, e.g.*, *supra* ¶¶ 46-47.

American people, and without having full access to the data to which they are entitled, Americans cannot judge whether all of those actions were justified. This presents a grave risk if this country is ever confronted with a similar declared emergency in the future. Hindsight is 20/20 only if all of the data is out in the open.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court order the FDA to produce all documents responsive to the Pfizer 12-15 request on or before October 15, 2023 and all documents responsive to the Moderna request on or before April 15, 2025.

Dated: March 8, 2023

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Colin M. Farnsworth, OR Bar No. 213351
745 Fifth Avenue, Suite 500
New York, New York 10151
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com

Walker D. Moller, TX Bar No. 24092851
1005 Congress Ave., Suite 925-C36
Austin, TX 78701
Tel : (512) 265-5622
wmoller@sirillp.com

John C. Sullivan, TX Bar No. 24083920
SL LAW PLLC
610 Uptown Boulevard, Suite 2000
Cedar Hill, TX 75104
john.sullivan@the-sl-lawfirm.com
Tel: (469) 523-1351
Fax: (469) 613-0891

Attorneys for Plaintiffs