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

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, as for their Complaint regarding Freedom of Information Act requests against the above-captioned Defendant, allege as follows:

INTRODUCTION

1. On January 31, 2022, the Food and Drug Administration ("**FDA**") approved the Moderna COVID-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older.[1]

2. On July 8, 2022, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty, for individuals 12 through 15 years of age (the "**12-15-Year-Old Pfizer Vaccine**").[2]

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

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

3. For the Moderna Vaccine, 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."[3]

4. Similarly, for the 12-15-Year-Old Pfizer Vaccine, FDA asserts its "approval follows a rigorous analysis and evaluation of the safety and effectiveness data conducted by FDA."[4]

5. Despite FDA's assertions, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon by FDA to license the Moderna Vaccine and the 12-15-Year-Old Pfizer Vaccine (the "**COVID-19 Vaccines**").

6. Plaintiff Public Health and Medical Professionals for Transparency ("**PHMPT**") is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files of each of the COVID-19 vaccines.

7. In furtherance of its mission, and in an effort to ensure that FDA acts in furtherance of its commitment to transparency,[5] PHMPT previously sought to obtain the data and information relied upon to license Comirnaty, Pfizer's COVID-19 vaccine for individuals 16 years of age and older. As a result of an Order from this Court, FDA is currently producing that data which PHMPT makes available to the public as it is produced.

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

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

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

8. PHMPT now seeks to obtain additional data and information relied upon by FDA to license the COVID-19 Vaccines. The importance of releasing this information to the public is also 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 . . . ." 21 C.F.R. § 601.51(e).

9. Upon licensure for each of the COVID-19 Vaccines, PHMPT therefore 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] enumerated in 21 C.F.R. § 601.51(e)[6] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System."[7]

10. A near identical request for the 12-15-Year-Old Pfizer Vaccine was later submitted to FDA by Patrick and Stephanie de Garay (the "**de Garays**"), parents of minor M.D., who suffered substantial injuries from a serious and ongoing adverse reaction to the 12-15-Year-Old Pfizer Vaccine during her participation in Pfizer's clinical trial for 12- to 15-year-olds.[8]

11. The public and the medical and scientific community have a substantial interest in reviewing the data and information underlying FDA's approval of the COVID-19 Vaccines.

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[6] 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]."

[7] 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.

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

12. Releasing this data should also confirm FDA's conclusion that the COVID-19 Vaccines are safe and effective and, thus, further the FDA's mission to increase confidence in the COVID-19 Vaccines and their uptake.

13. The public's need for this information is urgent given the fact that the COVID-19 Vaccines have been, or continue to be, mandated for large segments of the American public. Moreover, both public and private policy makers continue to adjust their vaccine policies based on the information that is publicly available and publicized by influential participants on both sides of the ongoing public debate regarding the COVID-19 Vaccines' safety and effectiveness.

14. With legislators, policy makers, and parents deciding how best to protect Americans of all ages during the upcoming winter season and academic school year, there is no more urgent or appropriate time for the immediate disclosure of the COVID-19 Vaccines' biological product files ("**BLA files**"). The public's value in the release of the BLA files would be significantly diminished if the disclosure were delayed because millions of Americans, and their policy makers, will be making these medical and policy decisions in the coming months. If the disclosure of the BLA files is delayed, many of these Americans, and many on behalf of their children, will be forced to make irreversible medical decisions before the independent scientific community and journalists have had time to review and report upon the basis for FDA's licensure of the COVID-19 Vaccines.

15. In an effort to disseminate the requested information to the public as expeditiously as possible, given the time sensitive nature of the issue, both PHMPT and the de Garays (collectively, the "**Plaintiffs**") requested expedited processing of the FOIA requests pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

16. On March 7, 2022, FDA denied PHMPT's request for expedited processing of its FOIA request regarding the Moderna Vaccine. PHMPT appealed the decision on June 1, 2022 and FDA still has not resolved that appeal.

17. On August 15, 2022, FDA denied PHMPT's request for expedited processing for its FOIA request regarding the 12-15-Year-Old Pfizer Vaccine.

18. Similarly, on August 29, 2022, FDA denied the de Garays' request for expedited processing of their FOIA request regarding the 12-15-Year-Old Pfizer Vaccine.

19. The Plaintiffs bring this action to challenge FDA's determinations and to seek an order compelling FDA to produce responsive records on an expedited basis.

PARTIES

20. Public Health and Medical Professionals for Transparency is a not-for-profit organization with an office located at 1090 Texan Trail, Suite 534, Grapevine, Texas, 76051 in Tarrant County, Texas.

21. To date, PHMPT has approximately 5,865 members, including medical and public health professionals, such as 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, The Warren Alpert Medical School of Brown University, Oregon Health & Science University, University of California San Francisco, David Geffen School of Medicine at UCLA, University of Leicester, University of Southern Denmark, The University of Sydney, University of Oxford, Institute for Scientific Freedom, University of Toronto, University of Auckland, University of Muenster, and Deutenomics Science Institute, as well as other universities and journalists.

22. Patrick and Stephanie de Garay reside in Clermont County, Ohio and are the parents of 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.

23. FDA is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

I. FDA Licensure of COVID-19 Vaccines

25. 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" and "effective."[9] 21 C.F.R. 601.2(a).

26. In order to demonstrate that they are safe and effective, Pfizer and Moderna conducted clinical trials for each of their COVID-19 vaccines and reported results of those trials, as well as other studies, to the FDA as part of their products' BLA files.

[9] 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.

A. FDA Licensure of Pfizer's Comirnaty Vaccine and PHMPT's Related Case

27. Upon licensure of Pfizer's first COVID-19 vaccine, Comirnaty, for use in individuals 18 years and older, PHMPT submitted a FOIA request to obtain the data within the product's BLA file. Like in the instant action, PHMPT's expedited processing request was denied and PHMPT commenced a litigation, *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, 4:21-cv-01058-P, in this Court to obtain the documents from FDA.

28. On January 6, 2022, this Court ordered FDA to produce the responsive documents from Comirnaty's BLA file at a rate of 55,000 pages every 30 days until production is complete. The parties subsequently agreed to, and the Court ordered, slight modifications of the production schedule; however, the parties maintained the rate of 55,000 pages every 30 days for a majority of the production. That BLA file is currently being produced and, to date, has resulted in approximately 470,614 pages of documents being made public.

29. The public has shown great interest in these documents. To date, and as explained further below, there have been approximately three-quarters of a million downloads of the documents and data released and PHMPT's website itself has drawn over 2.7 million visitors and 4.5 million views in the last 12 months.

30. Once the entirety of the BLA file has been produced, independent experts and researchers will be able to conduct their own analyses about the efficacy of the vaccine.

B. FDA's Licensure of Pfizer's 12-15-Year-Old Vaccine and Moderna's Vaccine

31. Following the start of the clinical trials for Pfizer's vaccine for persons 16 years of age and older, Pfizer conducted clinical trials in children ages 12 to 15 years old.

32. The Plaintiffs' daughter, M.D., was one of the participants in Pfizer's clinical trials for the 12-15-Year-Old Pfizer Vaccine.[10] In fact, she was one of only approximately 1,000 children in this age range who were injected with the investigational vaccine. Within 24-hours of receiving the second dose of the vaccine during the clinical trial, M.D. 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.[11] M.D. was subsequently admitted to the hospital and later discharged with the diagnosis that her symptoms were the result of adverse reaction to the vaccine.[12] 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.[13] 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 12-15-Year-Old Pfizer Vaccine was categorized as "functional abdominal pain."[14]

33. Notwithstanding the de Garays' reporting of their daughter's wide range of severe symptoms, Pfizer's inaccurate and misleading characterization thereof, and the safety alarms that this should have been ringing, FDA granted the vaccine EUA and subsequently licensed the use of the 12-15-Year-Old Pfizer Vaccine on July 8, 2022.[15]

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[10] *See* Patrick de Garay's Declaration (**Exhibit 7** at pages 9-10.)

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

[12] *Id*.

[13] *See generally id.*

[14] *Id*. at 1:04:40

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

34. The Moderna Vaccine was likewise licensed by the FDA on January 31, 2022.[16]

35. The Code of Federal Regulations 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 . . ." 21 C.F.R. § 601.51(e) (emphasis added).

36. There is an ongoing, national public debate regarding the adequacy of the data and information, and analyses of same, relied upon by FDA to license the COVID-19 Vaccines.

37. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine is more than sufficient for licensure.

38. For example, in a press release issued on January 31, 2022, then-acting FDA Commissioner Janet Woodcock stated,

> The public can be assured that Spikevax [the Moderna Vaccine] meets the FDA's high standards for safety, effectiveness, and manufacturing quality required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[17]

Peter Marks, MD, PhD, the Director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

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

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

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax [the Moderna Vaccine]. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities. Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[18]

39. Even prior to FDA's approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[19]

40. For the 12-15-Year-Old Pfizer Vaccine, FDA asserts that its approval followed "a rigorous analysis and evaluation of the safety and effectiveness data conducted by FDA"[20] and the Center for Disease Control and Prevention ("**CDC**") currently "recommends COVID-19 vaccines for everyone 6 months and older and boosters for everyone 5 years and older." Furthermore, CDC states generally[21] that

> COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in the U.S. history. Evidence from hundreds of millions of COVID-19 vaccines already administered in the United States, and billions of vaccines administered globally, demonstrate that they are safe and effective.

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[18] *Id.*

[19] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html; *see also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving."); https://www.doh.wa.gov/Emergencies/COVID19/Vaccine-Information/Safety-and-Effectiveness ("COVID-19 vaccines are safe.").

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

[21] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html.

41. On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon to the license the COVID-19 Vaccines, including a number of scientists and journalists who are members of PHMPT.

42. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, PhD, Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[22] and Peter A. McCullough, MD, former Professor of Medicine at Texas A&M College of Medicine, filed a Citizen Petition[23] with FDA, stating that the available evidence for licensure of the COVID-19 Vaccines "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[24] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[25] which Peter Marks, MD, PhD, Director of FDA's Center for Biologics Evaluation and Research, publicly disputed.[26]

43. More recently, 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

[22] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi.

[23] https://www.regulations.gov/document/FDA-2021-P-0521-0001.

[24] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/.

[25] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/; https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/; https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/.

[26] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/.

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**."[27]

44. Numerous other recent papers have presented data that have called into serious question the efficacy of these vaccines, including data that reflect issues which should have been seen during the clinical trial if it had been conducted properly and the results 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.[28]

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.[29]

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

[27] *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).

[28] *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.

[29] *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).

study found waning vaccine protection against symptomatic COVID-19 from 27 days after the second dose.[30]

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 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."[31]

e. A study printed in *JAMA*, which was 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."[32]

45. Likewise, numerous recent papers have presented data of serious safety issues with these vaccines, including data that reflect issues which should have been seen during the clinical

[30] *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/.

[31] *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.

[32] *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/.

trial if it had been conducted properly and the results fully reported to the FDA, including immune, neurological and circulatory system disorders. For example, 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.[33]

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.[34]

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." [35]

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[33] 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/.

[34] 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.

[35] 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.[36]

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.[37]

II. Vaccine Mandates

46. The public debate over the safety and effectiveness of the COVID-19 Vaccines concerns matters of current exigency to the American public because it has also led to invasive policy decisions that affect the livelihoods of the American public. Over the objections of many, Americans are still being mandated or otherwise pressured to take this product by the federal

[36] 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.

[37] 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.

government,[38] local governments,[39] public and private employers,[40] universities,[41] schools,[42] and various other institutions.[43]

47. Furthermore, now that FDA has approved the 12-15-Year-Old Pfizer Vaccine, there are many indications that states and school districts will begin mandating these vaccines for

[38] *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.

[39] *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.

[40] *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.

[41] *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.

[42] *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-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/.

[43] *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/.

children to attend public school.[44] Washington, D.C. has already announced a mandate for students ages 12 and older.[45]

III. PHMPT's FOIA Request for the Moderna Vaccine's BLA File

48. In furtherance of PHMPT's mission to disseminate information to the public, and in an effort to ensure that FDA acts consistent with its commitment to transparency,[46] 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)[47] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[48]

(**Exhibit 1**.)

49. 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

[44] 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.

[45] *See* https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087.

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

[47] 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]."

[48] 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.

> 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.

(**Exhibit 2**.)

50. On June 1, 2022, PHMPT submitted an appeal challenging FDA's decision to deny PHMPT's requests for Expedited Processing. (**Exhibit 3**.)

51. 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. (**Exhibit 4**.)

52. 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.

IV. PHMPT's FOIA Request for the 12-15-Year-Old Pfizer Vaccine's BLA File

53. In furtherance of PHMPT's mission to disseminate information to the public, and in an effort to ensure that FDA acts consistent with its commitment to transparency,[49] PHMPT 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):

> All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[50] with the exception of

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

[50] 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]."

> publicly available reports on the Vaccine Adverse Events Reporting System.[51]
>
> 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.

(Exhibit 5.)

54. 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.

(**Exhibit 6**.)

V. The de Garays' FOIA Request

55. In furtherance of the de Garays' advocacy for their vaccine-injured daughter, as well as their public advocacy in educating the public of the serious adverse events children may experience after receiving the 12-15-Year-Old Pfizer Vaccine, and in an effort to ensure that FDA acts consistent with its commitment to transparency,[52] the de Garays submitted the following request to FDA on August 22, 2022 and sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II)::

[51] 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.

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

> All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[53] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[54]
>
> This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (as that will be publicly available) 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.

(Exhibit 7.)

56. 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:

> 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.

(**Exhibit 8**.)

ARGUMENT

57. FOIA provides for "expedited processing of request for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). As defined by FOIA, a "compelling need"

[53] 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]."

[54] 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.

is justified when the person requesting information is (A) "primarily engaged in disseminating information" and (B) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

58. When an agency denies a request for expedited processing, the decision is subject to immediate judicial review. 5 U.S.C. § 522(a)(6)(E)(iii). A requester is not required to pursue an administrative appeal before seeking judicial review of its request for expedited processing of a FOIA request. *Elec. Privacy Info. Ctr. v. Dep't of Defense*, 355 F. Supp. 2d 98, 100 (D.D.C. 2004).

59. Therefore, as demonstrated above,[55] Plaintiffs are authorized to bring this action because their requests for expedited processing have been denied by FDA.

60. Furthermore, as explained below, both Plaintiffs can demonstrate a "compelling need" for the expedited processing of their FOIA requests. 5 U.S.C. § 552(a)(6)(E)(i)(I); 5 U.S.C. § 552(a)(6)(E)(v)(II).

I. Plaintiffs Are Primarily Engaged in Disseminating Information

61. In this instance, FDA's Denial Letters do not challenge the Plaintiffs' claims that they are primarily engaged in disseminating information.

62. PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 Vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms, as it has with the Comirnaty data. Many of PHMPT's individual members, including all of its

[55] *See, e.g.*, *supra* ¶¶ 48-52

members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews,[56] articles,[57] blogs,[58] essays,[59] and podcasts.[60] PHMPT and its members fully intend to analyze and disseminate the data and information underlying the licensure (or FDA "approval") of the COVID-19 Vaccines, that it hopes to receive from its FOIA requests.

63. The de Garays have become influential public advocates in educating the public on the serious adverse events children may experience after receiving the 12-15-Year-Old Pfizer Vaccine. Their advocacy began shortly after their daughter, M.D., who was a participant in the clinical trials for the 12-15-Year-Old Pfizer Vaccine,[61] suffered the extreme adverse reaction that ultimately necessitated her continued use of a feeding tube and wheelchair.[62] As part of the de Garays' public advocacy, they have worked with a number of media organizations including Fox

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[56] *See, e.g.*, https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role (Harvey Risch).

[57] *See, e.g.*, https://www.bmj.com/content/373/bmj.n1244 (Peter Doshi); https://www.bmj.com/content/371/bmj.m4058 (Peter Doshi); https://www.bmj.com/content/371/bmj.m4037 (Peter Doshi); https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749; https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (Aaron Kheriaty and Gerard V. Bradley); https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/ (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley); https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/ (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch); https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf (Serena Tinari and Catherine Riva); https://www.bmj.com/content/372/bmj.n627 (Serena Tinari); https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735 (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi); https://www.arcdigital.media/p/medical-ethicist-sues-the-university (Justin Lee).

[58] *See, e.g.*, https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (Peter Doshi); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (Peter Doshi); *see also* https://www.re-check.ch/wordpress/en/covid-certificate/ (Catherine Riva and Serena Tinari).

[59] *See* https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/ (Andrew Bostom).

[60] *See, e.g.*, https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/(Andrew Bostom).

[61] *See* Patrick de Garay's Declaration (**Exhibit 7 at pages 9-10**.)

[62] https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair.

News and the Highwire, as well as advocacy groups, that have and will continue to disseminate their story. These include:

a. June 28, 2021: Appearance on Senator Ron Johnson's press conference with individuals who suffered adverse reactions to COVID-19 vaccines.[63]

b. June 29, 2021: Federalist Article: "Twitter Censors Video of Mother Describing Daughter's COVID-19 Vaccine Side Effects."[64]

c. July 1, 2021: Coverage of testimony at Senator Ron Johnson press conference by Tucker Carlson Tonight.[65]

d. July 2, 2021: Appearance on Tucker Carlson Tonight.[66]

e. November 2, 2021: Appearance on Senator Ron Johnson's Expert Panel on Federal Vaccine Mandates.[67]

f. December 12, 2021: Australian Senator Gerard Rennick Facebook post on de Garay testimony.[68]

g. January 12, 2022: Discussion of de Garays by podcast host Joe Rogan on the Joe Rogan Experience.[69]

h. January 27, 2022: Interview by Epoch Times.[70]

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[63] https://youtu.be/lAeVLdMnerQ?t=1885.

[64] https://thefederalist.com/2021/06/29/twitter-censors-video-of-mother-describing-daughters-covid-19-vaccine-side-effects/.

[65] https://www.foxnews.com/transcript/tucker-people-in-charge-create-disaster-after-disaster at 12:00.

[66] https://video.foxnews.com/v/6262045756001#sp=show-clips.

[67] https://rumble.com/vokrf7-sen.-johnson-expert-panel-on-federal-vaccine-mandates.html at 22:25.

[68] https://www.facebook.com/watch/?v=637650331001531.

[69] https://rumble.com/vsgwe2-joe-rogan-on-maddie-de-garay-and-suppression-of-vaccine-adverse-events..html.

[70] https://www.theepochtimes.com/the-vaccine-injured-and-their-fight-for-treatment-transparency-trial-participants-stephanie-and-maddie-de-garay-and-brianne-dressen_4241609.html?welcomeuser=1.

i. April 7, 2022: Interview on Operation Mama Bears.[71]

j. April 10, 2022: Appearance at Defeat the Mandates Rally at Grand Park, Los Angeles, CA.[72]

k. May 5, 2022: Interview on Broken Truth.[73]

l. June 28, 2022: Interview on Blaze Media's Conservative Review.[74]

m. August 13, 2022: Appearance on The HighWire, "Rigged: Maddie's Story."[75]

64. Therefore, both Plaintiffs are "primarily engaged in disseminating information to the general public." 5 U.S.C. § 552(a)(6)(E)(v)(II).

II. There Is an Urgency to Inform the Public Concerning Actual or Alleged Federal Government Activity

65. First, 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 . . . ." 21 C.F.R. § 601.51(e) (emphasis added). 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." *Id.* 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.

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[71] https://www.youtube.com/watch?v=25kYj80Wn-g.

[72] https://rumble.com/v10yrh1-vaccine-injured-speak-out-at-defeat-the-mandates-los-angeles-ca.html at 7:00.

[73] https://brokentruth.com/108-clinical-trials-harm-kids/.

[74] https://www.iheart.com/podcast/263-the-conservative-co-28419175/episode/the-full-story-of-maddie-de-98826546/.

[75] https://thehighwire.com/videos/rigged-maddies-story/.

66. 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" and "effective."[76] 21 C.F.R. § 601.2(a). To assure FDA's commitment to transparency,[77] 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 and information after a product is licensed, absent any extraordinary circumstances. This is the same information that would be responsive to the Plaintiffs' requests.

67. Beyond FDA's own regulations which admit the urgent need for transparency and disclosure for the requested information, there are two additional reasons that warrant expedited treatment of this request.

68. First, as explained above,[78] there is an ongoing, national public debate regarding the adequacy of the data and information, and analyses of same, relied upon by FDA to license the COVID-19 Vaccines.

69. Although public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that 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

[76] 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.

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

[78] *See, e.g.*, *supra* ¶¶ 36-45.

figures, and others with large social or 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.

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

71. 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 Vaccine 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.[79]

72. While the presence of these mandates continues to fluctuate over the course of the various stages of the COVID-19 pandemic, at the federal level, the Pentagon has continued to mandate COVID-19 vaccines for all military personnel.[80]

73. The urgency regarding the safety and effectiveness information is especially relevant for United States Military. Despite the passage of deadlines for active-duty members to receive the COVID-19 vaccines, tens-of-thousands of active-duty service members refuse to get them.[81]

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[79] *See, e.g.*, *supra* ¶¶46-47.

[80] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military/; *see also* https://www.nbcnews.com/news/military/deadline-passes-one-10-army-national-guard-soldiers-still-unvaccinated-rcna36269.

[81] https://www.forbes.com/sites/teakvetenadze/2021/12/15/military-starts-ejecting-unvaccinated-service-members/?sh=7981d3146ed0.

74. Most recently, the Army announced roughly 40,000 National Guardsmen and 22,000 reservists will be barred from service for refusing to get vaccinated against COVID-19. This decision effectively cuts off the pay and benefits for more than 60,000 service members and prohibits them from participating in training.[82]

75. These separations of service members ironically come at a time when the military faces serious recruiting challenges.[83] For example, after the first five months of 2022, the Army reached only 23% of its active-duty goal for new recruits, and the Air Force obtained 2,300 fewer recruits in the first fiscal quarter than it did in 2021.[84] Army Gen. Joseph Martin, Vice Chief of Staff for the Army, has stated that, if these short falls continue, they may have an impact on the military's readiness.[85]

76. With regards to the 12-15-Year-Old Pfizer Vaccine, after its FDA approval, policy makers are reviewing the available information to determine if COVID-19 vaccine requirements are appropriate for students for the 2022-2023 school year, and beyond.[86]

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

78. 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

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[82] https://nypost.com/2022/07/08/army-cuts-pay-from-over-60k-unvaccinated-national-guard-reserves/.

[83] https://thehill.com/opinion/national-security/3527921-the-military-has-a-serious-recruiting-problem-congress-must-fix-it/; *see also* https://www.military.com/daily-news/2022/07/06/army-cuts-off-more-60k-unvaccinated-guard-and-reserve-soldiers-pay-and-benefits.html.

[84] *Id.*

[85] https://www.pbs.org/newshour/politics/army-cuts-expected-force-size-amid-unprecedented-shortfall-of-recruits.

[868686] *See, e.g.*, *supra* ¶¶ 46-47.

employment, school, transportation, restaurants, entertainment facilities, and the military, the public has an urgent and immediate need to have access to this data.

79. Finally, the information Plaintiffs seek concerns actual or alleged federal government activity – namely, whether FDA properly approved the COVID-19 Vaccines based on adequate data and information. Additionally, Plaintiffs' requests concern FDA's regulatory obligation to make parts of the COVID-19 Vaccines BLA file "immediately available for public disclosure" once a license has been issued.[87] Such parts include all safety and effectiveness data and information,[88] which is precisely the information Plaintiffs' FOIA requests seek on an expedited basis. (**Exhibit 1, 5** & **8**.)

80. The general public's interest in the data sought by the Plaintiffs' requests has already been demonstrated by the public's engagement with the ongoing release of similar data from PHMPT's litigation to disclose the BLA file for Pfizer's COVID-19 vaccine, Comirnaty.[89] The data produced by FDA has been made public on PHMPT's website. Despite the fact that only a portion of the data has been released, and hence is not yet ready for proper analysis by the public, there have been approximately three-quarters of a million downloads of the documents and data released to date by members of the public. The website itself has drawn over 2.7 million visitors and 4.5 million views in the last 12 months which makes clear that the public, and especially individuals involved in healthcare, have a sincere interest in viewing the documents considered by the FDA in approving Pfizer's COVID-19 vaccine and the legal process which led to their release.

81. Therefore, Plaintiffs have demonstrated that they are primarily engaged in disseminating information and that there is an urgency to inform the public concerning actual or

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[87] 21 C.F.R. § 601.51(e).

[88] *Id*.

[89] *See, e.g.*, *supra* ¶¶ 27-30.

alleged Federal Government activity and, thus, FDA should provide expedited processing for the requested records because Plaintiffs have a "compelling need". 5 U.S.C. § 552(a)(6)(E)(i)(I).

REQUESTED RELIEF

WHEREFORE, Plaintiffs pray that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an order directing FDA to produce all responsive documents at the rate of 55,000 pages per month after the FDA completes its production in the related case, *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, Index No. 4:21-cv-01058-P;

c. Award Plaintiffs their costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

d. Grant such other and further relief as the Court may deem just and proper.

Dated: October 11, 2022

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Exhibit 1

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FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL February 23, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Moderna COVID-19 Vaccine Biological Product File (IR#0710)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On January 31, 2022, the Food and Drug Administration ("**FDA**") approved the Moderna[1] COVID-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[2] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[3]**

[1] For purposes of this request, Moderna shall be interpreted to include Moderna, Inc. and any of its parents, subsidiaries and affiliates.

[2] 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]."

[3] 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.

I. EXPEDITED PROCESSING REQUESTED

PHMPT requests expedited processing for this request as it meets the requirements for expedited processing under both FDA's FOIA Regulations as well as FOIA itself.

A. PHMPT Qualifies for Expedited Processing Under FOIA

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

Here, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews, articles, blogs, essays, and podcasts. Therefore, PHMPT and many of its members are "primarily engaged in disseminating information [] to inform the public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," which in this case is the data and information underlying the licensure of the Moderna Vaccine. Accordingly, expedited processing of this request under FOIA is warranted.

B. PHMPT Qualifies for Expedited Processing Under the FDA's FOIA Regulations

Notably, separate and apart from the FDA's obligation to comply with FOIA, it has an independent duty to inform the public concerning the data and information underlying a licensed vaccine. The FDA's Regulations expressly provide 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 . . ." 21 C.F.R. § 601.51(e)(1) (emphasis added). Thus, the 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." *Id.* This policy supports the FDA's claimed commitment to,[4] and assurances of, transparency[5] as a lack of transparency erodes the confidence the medical and scientific communities and the public have in the conclusions reached by the FDA. However, the fact that the FDA did not release the documents following licensure necessitated this FOIA request.

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[4] https://www.fda.gov/news-events/press-announcements/covid-19-update-fdas-ongoing-commitment-transparency-covid-19-euas (last visited 2/19/2022).

[5] https://www.fda.gov/about-fda/transparency/transparency-initiative (last visited 2/19/2022); https://www.fda.gov/news-events/speeches-fda-officials/fostering-transparency-improve-public-health (last visited 2/19/2022).

But aside from the FDA's duty to make immediately available the safety and effectiveness data of a licensed vaccine, the FDA's FOIA regulations anticipate scenarios where FOIA requests must be expedited. Specifically, a requestor is entitled to expedited processing where:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c)(1)-(3).

PHMPT easily meets all three requirements. As noted above, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists that was created and exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. Therefore, PHMPT is certainly "primarily engaged in disseminating information to the general public." 21 C.F.R. § 20.44(c)(1).

Next, there is plainly an urgent public need for transparency with regard to the data relied upon in licensing the Moderna Vaccine for at least two distinct reasons beyond the FDA's own regulations which admit the urgent need for transparency and disclosure of this information. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the 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" and "effective."[6] 21 C.F.R. 601.2(a). There is, however, an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the COVID-19 vaccines, including the Moderna Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine is more than sufficient for licensure. For example, in a statement released on January 31, 2022, acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality

[6] The 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 (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

> required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[7]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[8]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[9]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or 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 Moderna Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[10] and Peter A. McCullough, M.D. filed an amended Citizen Petition[11] with the FDA, claiming that the available evidence for licensure of the

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[7] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html.

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

[9] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 02/19/2022). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[10] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[11] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[12] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[13] which Dr. Peter Marks publicly disputed.[14] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[15] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[16] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[17] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public."[18] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Moderna Vaccine.

Secondly, and perhaps even more significantly, there is an urgent need for the public to have immediate access to the data and information underlying the licensure of the Moderna Vaccine because, over the objections of many, this product is being mandated to individuals across

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[12] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 02/19/2022).

[13] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 02/19/2022).

[14] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[15] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[16] https://www.fda.gov/media/150054/download (last visited 02/19/2022)

[17] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[18] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

the country by the federal government,[19] local governments, [20] public and private employers,[21] universities, [22] schools,[23] and various other institutions,[24] and many are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[25] and the Pentagon has mandated the COVID-19 vaccines

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[19] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); 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 (last visited 2/19/2022); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 02/19/2022).

[20] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[21] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[22] *See* (last visited 02/19/2022). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[23] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); 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 (last visited 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[24] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 2/19/2022); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[25] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

for all military personnel.[26] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[27] all state employees, [28] and even for all citizens of various states.[29] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[30] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[31] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it. Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. Therefore, for all of these reasons, PHMPT has shown there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly." 21 C.F.R. § 20.44(c)(2).

Finally, PHMPT's request meets the third requirement for expedited processing – that "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(3). Here, PHMPT's records request specifically concerns identifiable activities—i.e., approval of the Moderna Vaccine—by the Federal Government—to wit, the FDA.

In light of the above, PHMPT has demonstrated that its request qualifies for expedited processing under both the FDA's FOIA regulations, as well as FOIA itself. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications

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[26] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[27] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

[28] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 02/19/2022).

[29] *See* New York bill A11179, available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 02/19/2022).

[30] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[31] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

regarding or reflecting the public discussion, discourse, and debate regarding the mandating or potential mandating of the Moderna Vaccine. PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

II. FEE WAIVER REQUEST

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Moderna Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that in the event only a portion or portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Exhibit 2

U.S. FOOD & DRUG ADMINISTRATION

March 07, 2022

In Reply refer to
FOIA Control #:
2022-1614

Requester reference:
IR#0710

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information 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. See letter for further details.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

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. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

Exhibit 3

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER

200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FDA FREEDOM OF INFORMATION ACT APPEAL
EXPEDITED PROCESSING

VIA EMAIL June 1, 2022

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: ***Expedited Processing Appeal of FOIA Control #2022-1614 (IR#0710)***

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**"). On behalf of PHMPT, on February 23, 2022, we requested records on an expedited basis from the files of the Food and Drug Administration ("**FDA**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FDA designated the request as FOIA Control #2022-1614 (the "**FOIA Request**"). In a letter dated March 7, 2022, the FDA denied PHMPT's request for expedited processing (the "**Denial Letter**"). PHMPT writes now to appeal that determination.

A. The FOIA Request

On February 23, 2022, PHMPT submitted the FOIA Request to the FDA for the following documents:

> All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

[1] 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]."

(**Exhibit 1**.)[2]

In the FOIA Request, PHMPT requested that the FDA expedite processing for this request pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II) and provided detailed reasons for requesting expedited processing. (**Exhibit 1**.)

On March 1, 2022, FDA acknowledged the FOIA Request and assigned it Request Number #2022-1614. On March 7, 2022, FDA and denied PHMPT's request for expedited processing. (**Exhibit 2**.) The denial letter stated in relevant part:

> The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."
>
> 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. The responding agency office will process your request in the order in which it was received.

(**Exhibit 3**).

B. Argument

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

PHMPT requested expedited processing of the FOIA Request on the basis that it is "primarily engaged in disseminating information" and that there is an "urgency to inform the public concerning actual or alleged Federal Government activity." PHMPT demonstrated in its FOIA Request that it exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. (**Exhibit 1**.) That

[2] All "Exhibits" referenced herein are appended to this letter.

fact was not challenged by the FDA in its Denial Letter and, therefore, this appeal, focuses solely on the FDA's claim that PHMPT failed to demonstrate "there exists an urgency to inform the public concerning actual or alleged Federal Government activity." (**Exhibit 3.**) For the purposes of this appeal PHMPT fully incorporates all of the arguments, references, and citations exhaustively detailed in its FOIA Request for expedited processing.

Contrary to FDA's assertions, as set forth in PHMPT's FOIA Request, there exists an urgency to inform the public concerning actual or alleged Federal Government activities. In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (i) whether the request concerns a matter of current exigency to the American public; (ii) whether the consequences of delaying a response would compromise a significant recognized interest; and (iii) whether the request concerns federal government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of PHMPT's FOIA Request.

(i) PHMPT's request concerns a matter of current exigency to the American public

As to the first factor, PHMPT's FOIA Request concerns a matter of current exigency to the American public. PHMPT's FOIA Request is for the Moderna Vaccine's biological product file, available under 21 C.F.R. § 601.51(e). The FDA itself acknowledges the exigency in releasing the biological product file in the Code of Federal Regulations, which expressly provides that "[a]fter a license has been issued . . . data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown." 21 C.F.R. § 601.51(e) (emphasis added). Under this regulation, a critical part of the biological product file that must be released is "all safety and effectiveness data and information." 21 C.F.R. § 601.51(e)(1). Therefore, the FDA's own regulations acknowledge the current exigency in making the Moderna Vaccine's biological product file, including its safety and effectiveness data and information, immediately available for public disclosure. Thus, FDA's regulation not only supports the need for expedited treatment under FOIA, but it is also an independent legal basis that requires expedited treatment of the FOIA Request.

Beyond the FDA's own regulations recognizing the exigency of records sought in PHMPT's FOIA request, there are other reasons why such exigencies exist. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393. The 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" and "effective."[3] 21 C.F.R. 601.2(a). There is, however, an ongoing public national debate regarding the adequacy of the data, information, and analyses relied upon by the FDA to license the Moderna Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine

[3] The 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 (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

is more than sufficient for licensure. For example, in a statement released on January 31, 2022, then-acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[4]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[5]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[6]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon to license the Moderna Vaccine, including a number of scientists and journalists who are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[7] and Peter A. McCullough, M.D. filed an amended Citizen Petition[8] with the FDA, claiming that the available evidence for licensure

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[4] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html (last visited 03/16/22).

[5] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine (last visited 03/16/22).

[6] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 02/19/2022). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[7] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[8] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

of the Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[9] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[10] which Dr. Peter Marks publicly disputed.[11] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[12] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[13] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[14] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public."[15] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. The FOIA Request attempts to expedite the disclosure of this critical information. Therefore, PHMPT's FOIA Request concerns a matter of current exigency to the American public.

Secondly, this public debate over the safety and effectiveness of the Moderna Vaccine concerns matters of current exigency to the American public because it has led to invasive policy decisions that affect the livelihoods of the American public. Over the objections of many, this product is being mandated to individuals across the country by the federal government,[16] local

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[9] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 02/19/2022).

[10] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 02/19/2022).

[11] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[12] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[13] https://www.fda.gov/media/150054/download (last visited 02/19/2022).

[14] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[15] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

[16] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); 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 (last visited 2/19/2022);

governments,[17] public and private employers,[18] universities,[19] schools,[20] and various other institutions,[21] and many others are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[22] and the Pentagon has mandated COVID-19 vaccines for all military personnel.[23] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[24]

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https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 02/19/2022).

[17] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[18] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[19] *See e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[20] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); 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 (last visited 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[21] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 2/19/2022); https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[22] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

[23] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[24] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

all state employees, [25] and even for all citizens of several states.[26] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[27] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[28]

During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and the various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it.

Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. For all of these reasons, PHMPT has demonstrated its request significantly concerns matters of current exigency to the American public. Therefore, the first factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

(ii) Consequences in delaying a response would compromise significant recognized interests

With respect to the second factor in the "compelling need" analysis, the consequences of delaying a response to PHMPT's FOIA request would compromise significant recognized interests. As described above, the FDA's regulations recognize the public's interest in having aspects of the biological product file "immediately available for public disclosure." 21 C.F.R. § 601.51(e). The regulation specifically enables the public to see firsthand the safety and effectiveness data and information relating to the Moderna Vaccine. *Id*. This regulation, like many others that regulate public health and consumer products, is built on significant recognized

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[25] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 02/19/2022).

[26] *See* New York bill A11179, available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 02/19/2022).

[27] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[28] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

interests, such as "informed consent" and "consumer protection." This fact is further demonstrated by FDA's mission statements published on its website: "[T]he mission of FDA is to enforce laws enacted by the U.S. Congress and regulation established by the agency to protect the consumer's health, safety, and pocketbook"[29]; "FDA is responsible for advancing the public health by . . . helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."[30] Moreover, notions of informed consent have been codified in jurisdictions all across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent."[31]

A sense of trust is created when a product becomes licensed by the FDA, and therefore, as explained by Dr. Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine.[32] As anticipated, after the FDA's approval of Pfizer's COVID-19 vaccine, Comirnaty, President Biden actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[33]

Additionally, Moderna has recently requested EUA for its vaccines for children[34] and these requests are based on data that relate to the clinical trials used for Spikevax. The requested data underlies the immunobridging that is now occurring in the trials for children 6 months through 17 years of age and would shed light on the efficacy of those vaccines. Parents across the country are currently being faced with the decision of whether or not to vaccinate their children, whether or not to administer a booster to their child, and, if so, to choose which vaccine to administer. In order to make an informed decision and to give informed consent, all of the relevant data should be disclosed in a timely manner. Otherwise, these parents will be unable to make a truly informed choice until that happens.

The combination of COVID-19 vaccine mandates, additional EUAs being granted for different age groups, and the lack of disclosure regarding the determination of the products safety

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[29] https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-related-laws-regulations-and-guidances (last visited 03/16/22).

[30] https://www.fda.gov/about-fda/what-we-do (last visited 2/19/22).

[31] Tex. Civ. Prac. & Rem. Code § 74.101.

[32] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[33] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

[34] *See* https://www.cnn.com/2022/04/28/health/moderna-vaccine-eua-young-children/index.html and https://www.healio.com/news/primary-care/20220323/moderna-seeks-covid19-vaccine-authorization-for-kids-younger-than-6.

and effectiveness, violates the significant recognized interests of informed consent and consumer protection.

Without disclosure, consumers that are confronted with COVID-19 vaccine mandates are forced to choose between taking a vaccine without the science-based information necessary to make an informed decision, or losing their job, occupational benefits, access to medical procedures,[35] and access to educational opportunities.[36] Therefore, no matter a person's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the science-based information used to determine the Moderna Vaccine's safety and effectiveness compromises significant recognized interests: informed consent and consumer protection.

For the reasons set forth above, PHMPT has demonstrated that a delay of its FOIA request would compromise significant recognized interests. Thus, the second factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

(iii) PHMPT's request concerns federal government activity

Finally, the information PHMPT seeks clearly concerns actual or alleged federal government activity for at least two reasons. First, the FDA, a federal agency, has a regulatory obligation to release aspects of the Moderna Vaccine's biological product file such that it is "immediately available for public disclosure" after a license has been issued. 21 C.F.R. § 601.51(e). Such aspects include all safety and effectiveness data and information. *Id*.

Second, and perhaps most importantly, PHMPT's request concerns whether the FDA approved the Moderna Vaccine based on adequate data and information. PHMPT requested information relating to the federal licensing of the Moderna Vaccine. This particular request significantly concerns the federal government's activity since the federal government was not only involved in the licensure of the Moderna Vaccine but, crucially, the federal government was also heavily involved in the vaccine's research and development. According to the National Institutes of Health's (NIH) website:

> [B]ecause of [the] work that NIH was already doing when the COVID-19 pandemic began, researchers were able to come up with a vaccine for this new virus much faster . . .Years before the COVID-19 pandemic began, experts at the NIH Vaccine Research Center (VRC) were studying coronaviruses to find out how to protect against them . . . The VRC worked with a company called Moderna to use this information to quickly customize their prototypes approach to the SARS-CoV-2 spike protein. By early February [2020], a COVID-19 vaccine candidate had been designed and manufactured. This Vaccine is called mRNA 1273 . . . *the NIH-*

[35] https://www.bbc.com/news/world-us-canada-60132765 (last visited 03/16/22); https://www.wsoctv.com/news/local/i-will-die-free- unvaccinated-burke-county-man-denied-kidney-transplant-by-hospital/OJGAFURR4FGERJB7VT24P5RED4/ (last visited 03/16/22); https://www.nbc11news.com/2021/10/08/colorado-hospital-denies-unvaccinated-patient-transplant/ (last visited 03/16/22); https://www.foxnews.com/us/uva-hospital-refused-unvaccinated-transplant (last visited 03/16/22); https://www.businessinsider.com/ohio-woman-liver-disease-denied-transplant-vaccine-cleveland-clinic-2021-10.

[36] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

Moderna vaccine was authorized by the U.S. Food and Drug Administration (FDA) for emergency use. (emphasis added)[37]

The federal government's activities in designing and manufacturing the "NIH-Moderna vaccine" is particularly important because federal employees that were a part of its development and therefore are potential co-owners of the patents involved in the Moderna Vaccine. *See* U.S. Application No. 62/972,886 & No. 16/344,774; *see also* Research Collaboration Agreement 2017-1179 & "Material Transfer Agreement" executed on 12/16/2019.[38] Moreover, under 15 U.S.C. § 3710c, which regulates the "Distribution of royalties received by Federal agencies," federal agencies and their employees are authorized to profit from the licensing and assignment of inventions, such as the Moderna Vaccine. The federal government has already spent $6 billion helping develop, test, and manufacture the "NIH-Moderna vaccine."[39] The combination of potential conflicts of interest within the federal government itself, and the large sums of taxpayer money spent to obtain the FDA's approval of the Moderna Vaccine, requires immediate transparency into the federal government's activities. Thus, the third factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

PHMPT has demonstrated (i) the request concerns a matter of current exigency to the American public, (ii) the consequences of delaying a response would compromise a significant recognized interest, and (iii) the request concerns federal government activity. Therefore, PHMPT has reasonably established under FOIA a "compelling need" for the expedited processing of its request. 5 U.S.C. § 552(a)(6)(E)(v)(II)

C. Conclusion

Given the foregoing, ICAN hereby appeals and urges the FDA to grant its request for expedited processing within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact us at (212) 532-1091 or through email at foia@sirillp.com.

[37] https://covid19.nih.gov/news-and-stories/vaccine-development (last visited 03/16/22).

[38] https://www.citizen.org/article/the-nih-vaccine/#_ftn2 (last visited 03/16/22).

[39] https://www.statnews.com/2021/04/30/u-s-government-has-invested-6-billion-in-modernas-covid-19-vaccine/ (last visited 03/16/22).

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

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FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL February 23, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Moderna COVID-19 Vaccine Biological Product File (IR#0710)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On January 31, 2022, the Food and Drug Administration ("**FDA**") approved the Moderna[1] COVID-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[2] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[3]**

[1] For purposes of this request, Moderna shall be interpreted to include Moderna, Inc. and any of its parents, subsidiaries and affiliates.

[2] 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]."

[3] 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.

I. EXPEDITED PROCESSING REQUESTED

PHMPT requests expedited processing for this request as it meets the requirements for expedited processing under both FDA's FOIA Regulations as well as FOIA itself.

A. PHMPT Qualifies for Expedited Processing Under FOIA

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

Here, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews, articles, blogs, essays, and podcasts. Therefore, PHMPT and many of its members are "primarily engaged in disseminating information [] to inform the public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," which in this case is the data and information underlying the licensure of the Moderna Vaccine. Accordingly, expedited processing of this request under FOIA is warranted.

B. PHMPT Qualifies for Expedited Processing Under the FDA's FOIA Regulations

Notably, separate and apart from the FDA's obligation to comply with FOIA, it has an independent duty to inform the public concerning the data and information underlying a licensed vaccine. The FDA's Regulations expressly provide 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 . . ." 21 C.F.R. § 601.51(e)(1) (emphasis added). Thus, the 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." *Id.* This policy supports the FDA's claimed commitment to,[4] and assurances of, transparency[5] as a lack of transparency erodes the confidence the medical and scientific communities and the public have in the conclusions reached by the FDA. However, the fact that the FDA did not release the documents following licensure necessitated this FOIA request.

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[4] https://www.fda.gov/news-events/press-announcements/covid-19-update-fdas-ongoing-commitment-transparency-covid-19-euas (last visited 2/19/2022).

[5] https://www.fda.gov/about-fda/transparency/transparency-initiative (last visited 2/19/2022); https://www.fda.gov/news-events/speeches-fda-officials/fostering-transparency-improve-public-health (last visited 2/19/2022).

But aside from the FDA's duty to make immediately available the safety and effectiveness data of a licensed vaccine, the FDA's FOIA regulations anticipate scenarios where FOIA requests must be expedited. Specifically, a requestor is entitled to expedited processing where:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c)(1)-(3).

PHMPT easily meets all three requirements. As noted above, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists that was created and exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. Therefore, PHMPT is certainly "primarily engaged in disseminating information to the general public." 21 C.F.R. § 20.44(c)(1).

Next, there is plainly an urgent public need for transparency with regard to the data relied upon in licensing the Moderna Vaccine for at least two distinct reasons beyond the FDA's own regulations which admit the urgent need for transparency and disclosure of this information. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the 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" and "effective."[6] 21 C.F.R. 601.2(a). There is, however, an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the COVID-19 vaccines, including the Moderna Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine is more than sufficient for licensure. For example, in a statement released on January 31, 2022, acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality

[6] The 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 (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

> required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[7]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[8]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[9]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or 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 Moderna Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[10] and Peter A. McCullough, M.D. filed an amended Citizen Petition[11] with the FDA, claiming that the available evidence for licensure of the

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[7] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html.

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

[9] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 02/19/2022). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[10] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[11] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[12] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[13] which Dr. Peter Marks publicly disputed.[14] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[15] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[16] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[17] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public."[18] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Moderna Vaccine.

Secondly, and perhaps even more significantly, there is an urgent need for the public to have immediate access to the data and information underlying the licensure of the Moderna Vaccine because, over the objections of many, this product is being mandated to individuals across

[12] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 02/19/2022).

[13] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 02/19/2022).

[14] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[15] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[16] https://www.fda.gov/media/150054/download (last visited 02/19/2022)

[17] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[18] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

the country by the federal government,[19] local governments, [20] public and private employers,[21] universities, [22] schools,[23] and various other institutions,[24] and many are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[25] and the Pentagon has mandated the COVID-19 vaccines

[19] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); 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 (last visited 2/19/2022); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 02/19/2022).

[20] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[21] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[22] *See* (last visited 02/19/2022). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[23] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); 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 (last visited 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[24] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 2/19/2022); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[25] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

for all military personnel.[26] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[27] all state employees, [28] and even for all citizens of various states.[29] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[30] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[31] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it. Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. Therefore, for all of these reasons, PHMPT has shown there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly." 21 C.F.R. § 20.44(c)(2).

Finally, PHMPT's request meets the third requirement for expedited processing – that "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(3). Here, PHMPT's records request specifically concerns identifiable activities—i.e., approval of the Moderna Vaccine—by the Federal Government—to wit, the FDA.

In light of the above, PHMPT has demonstrated that its request qualifies for expedited processing under both the FDA's FOIA regulations, as well as FOIA itself. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications

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[26] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[27] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

[28] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 02/19/2022).

[29] *See* New York bill A11179, available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 02/19/2022).

[30] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[31] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

regarding or reflecting the public discussion, discourse, and debate regarding the mandating or potential mandating of the Moderna Vaccine. PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

II. FEE WAIVER REQUEST

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Moderna Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that in the event only a portion or portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Exhibit 2

U.S. FOOD & DRUG ADMINISTRATION

March 01, 2022

In Reply refer to
FOIA Control #:
2022-1614

Requester reference:
IR#0710

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All data and information 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. See letter for further details.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Wilson M. Russ, Freedom Of Information Specialist, at (301) 796-8981 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit 3

U.S. FOOD & DRUG ADMINISTRATION

March 07, 2022

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

In Reply refer to
FOIA Control #:
2022-1614

Requester reference:
IR#0710

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information 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. See letter for further details.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

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. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

Exhibit 4

Annalise Beube

From: FDA FOIA <FDAFOIA@fda.hhs.gov>
Sent: Wednesday, June 1, 2022 12:04 PM
To: S&G Information Request Staff; FDA FOIA
Subject: RE: [EXTERNAL] Expedited Processing Appeal of FOIA Control #2022-1614 (IR#0710)

Follow Up Flag: Follow up
Flag Status: Flagged

Appeal file: 22-0076AA

June 1, 2022

Sending via Email: foia@sirillp.com

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, submitted to the Food and Drug Administration (FDA). We received your appeal on June 1, 2022. Your appeal challenges the *Food and Drug Administration (FDA's)* response to your original request **#2022-1614**. Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Your appeal is summarized below:
Denial of Expedited Processing

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal. For more information about how your appeal will be processed please refer to the HHS FOIA regulations https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

The FOIA and the HHS FOIA regulations are available at the following web addresses: https://www.justice.gov/oip/freedom-information-act-5-usc-552 and https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations.

If you have any questions, please call (301)796-8975, or email us at fdafoia@fda.hhs.gov.

Sincerely yours,

Sarah Kotler
FDA FOIA

Sarah B. Kotler, J.D.
Director, Division of Freedom of Information

US FDA
301-796-8976

From: S&G Information Request Staff <foia@sirillp.com>
Sent: Wednesday, June 1, 2022 11:36 AM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Subject: [EXTERNAL] Expedited Processing Appeal of FOIA Control #2022-1614 (IR#0710)

Dear Sir or Madam,

Attached please find our client's appeal.

Thank you,

Annalise Beube, Law Clerk
Siri | Glimstad
700 S Flower Street
Suite 1000
Los Angeles, CA 90017
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

Exhibit 5

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

745 Fifth Ave, Suite 500, New York, NY 10151
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FDA FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL August 8, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Biological Product File for Comirnaty vaccine for 12-15 year-olds (IR#0820)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On July 8, 2022, the Food and Drug Administration ("**FDA**") approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty for individuals 12 through 15 years of age (the "**12-15-Year-Old Pfizer Vaccine**"). On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[2]**
>
> **This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (previously**

[1] 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]."

[2] 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.

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.

Expedited Processing Requested

PHMPT requests expedited processing for this request. FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews,[3] articles,[4] blogs,[5] essays,[6] and podcasts.[7] Therefore, PHMPT and many of its members are "primarily engaged in disseminating information to the general public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal

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[3] *See, e.g.*, https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role (Harvey Risch).

[4] *See, e.g.*, https://www.bmj.com/content/373/bmj.n1244 (Peter Doshi); https://www.bmj.com/content/371/bmj.m4058 (Peter Doshi); https://www.bmj.com/content/371/bmj.m4037 (Peter Doshi); https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749; https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (Aaron Kheriaty and Gerard V. Bradley); https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/ (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley); https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/ (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch); https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf (Serena Tinari and Catherine Riva); https://www.bmj.com/content/372/bmj.n627 (Serena Tinari); https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735 (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi); https://www.arcdigital.media/p/medical-ethicist-sues-the-university (Justin Lee).

[5] *See, e.g.*, https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (Peter Doshi); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (Peter Doshi). *See also* https://www.re-check.ch/wordpress/en/covid-certificate/ (Catherine Riva and Serena Tinari).

[6] *See* https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/ (Andrew Bostom).

[7] *See, e.g.*, https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/ (Andrew Bostom).

Government activity," here, the data and information underlying the licensure of the 12-15-Year-Old Pfizer Vaccine. Accordingly, expedited processing of this request is warranted.

Recognizing the urgency to inform the public concerning the data and information underlying a licensed vaccine, the Code of Federal Regulations 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…" 21 C.F.R. § 601.51(e) (emphasis added). The FDA's own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* The 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.

This policy is not surprising given the FDA's commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.[8] There is an urgent public need for such transparency with regard to the 12-15-Year-Old Pfizer Vaccine. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the 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" and "effective."[9] 21 C.F.R. 601.2(a). On July 8, 2022, the FDA granted approval to the 12-15-Year-Old Pfizer Vaccine[10] and, beyond the FDA's own regulations which admit the urgent need for transparency and disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the 12-15-Year-Old Pfizer Vaccine. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, senior editor for The BMJ and associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy,[11] and Peter A. McCullough, professor of medicine at Texas A&M College of Medicine, filed a Citizen Petition[12] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[13] Separately, Peter Doshi has publicly questioned the lack of

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

[9] The 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.

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

[11] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi.

[12] https://www.regulations.gov/document/FDA-2021-P-0521-0001.

[13] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/.

transparency regarding the vaccine approval process[14] which Peter Marks publicly disputed.[15] Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,[16] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[17] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[18] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[19] PHMPT incorporated by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse and debate regarding the 12-15-Year-Old Pfizer Vaccine, including all matters related to the licensure of this product.

More recently, a paper published on June 23, 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 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**."[20]

Many of these concerns also stem back to FDA's May 10, 2021 reissuance of the Emergency Use Authorization ("EUA") letter of authorization for use of Pfizer-BioNTech's COVID-19 in children ages 12 through 15.[21] These public debates have generated substantial evidence that calls into question the scientific justifications for FDA to issue an EUA for children 12 through 15 when (i) the data does not demonstrate that the known benefits outweigh the known risks and (ii) there are serious concerns regarding how the trials were conducted. These issues have been thoroughly cited and explained in a recent citizen petition filed with the Division of Dockets Management within the Department of Health and Human Services on May 20, 2022.[22] These concerns remain unsettled and part of the national debate. However, with the recent FDA approval

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[14] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/; https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/; https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/.

[15] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/.

[16] https://www.aaronkheriaty.com/bio.

[17] https://www.fda.gov/media/150054/download.

[18] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220.

[19] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf; *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/.

[20] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239 (emphasis added).

[21] https://www.fda.gov/media/144412/download.

[22] https://www.regulations.gov/document/FDA-2022-P-0872-0001.

of the 12-15-Year-Old Pfizer Vaccine, these concerns have generated even more urgency and importance. Large portions of the public have legitimate fears that FDA never fully demonstrated whether the known benefits outweigh the known risks[23] for this particular age group for the 12-15-Year-Old Pfizer Vaccine, or if the FDA corrected the serious concerns regarding how the 12-15-Year-Old Pfizer Vaccine trials were conducted.

Secondly, now that FDA has approved the 12-15-Year-Old Pfizer Vaccine, there are many indications that states and school districts will begin mandating these vaccines for children to attend public school.[24] Washington, D.C. has already announced a mandate for students ages 12 and older.[25] With legislators, policy makers, and parents deciding how best to protect children as they return to school this fall, there is no more urgent, or appropriate time for the immediate disclosure of the 12-15-Year-Old Pfizer Vaccine's biological product file ("**BLA file**"). The public's value in the release of the BLA file would be significantly diminished if the disclosure is delayed because millions of children, their parents, and their policy makers will be making medical decisions and policies in the coming months. If the disclosure of the BLA file is delayed, many of these children and parents will be forced to make irreversible medical decisions before the independent scientific community, and journalist have time to review, and report upon whether FDA resolved the outstanding concerns regarding its prior EUA when recently approving and licensing the 12-15-Year-Old Pfizer Vaccine.

In light of the above, PHMPT has demonstrated that its request qualifies for expedited processing under FOIA. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the mandating or potential mandating of the 12-15-Year-Old Pfizer Vaccine. PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

Fee Waiver Requested

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the 12-15-Year-Old Pfizer Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

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[23] https://www.floridahealth.gov/newsroom/2022/03/20220308-FDOH-covid19-vaccination-recommendations-children.pr.html.

[24] 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.

[25] *See* https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087.

Note that in the event only a portion or portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action. Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Exhibit 6

U.S. FOOD & DRUG ADMINISTRATION

August 15, 2022

SIRI & GLIMSTAD LLP
AARON SIRI
745 Fifth Ave.
New York NY 10151 US

In Reply refer to
FOIA Control #:
2022-5812

Requester reference:
IR#0820

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information 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.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

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. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

Exhibit 7

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

745 Fifth Ave, Suite 500, New York, NY 10151
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FDA FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL August 22, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: de Garays' request for Pfizer's BLA file for 12- to 15-year-olds (IR#0832)

Dear Sir or Madam:

This firm represents Patrick and Stephanie de Garay, parents of [redacted] de Garay (the "**de Garays**").

On July 8, 2022, the Food and Drug Administration ("**FDA**") approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty for individuals 12 through 15 years of age (the "**12-15-Year-Old Pfizer Vaccine**"). On behalf of the de Garays, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[2]**

[1] 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]."

[2] 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.

This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (as that will be publicly available) 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.

Expedited Processing Requested

The de Garays request expedited processing for this request. FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

The de Garays seek this information because their family has been deeply affected by the adverse reactions their daughter has suffered following receipt of the 12-15-Year-Old Pfizer Vaccine. Mr. and Mrs. de Garay's daughter, [redacted] ("[redacted]"), was a participant in Pfizer's clinical trial for the 12-15-Year-Old Pfizer Vaccine. (*See* de Garay Declaration, **Exhibit 1**). After receiving her second shot, [redacted] began suffering from an extreme adverse reaction that ultimately necessitated her use of a feeding tube and wheelchair.[3] Over a year and a half later, [redacted] is still suffering. Since this tragedy, the de Garays, who claim to be both "pro-vaccine, but also pro-informed consent" have become vocal advocates in alerting the public about the potential serious adverse reactions the 12-15-Year-Old Pfizer Vaccine may cause.[4] Thus, this is the primary reason they make this FOIA request.

As part of their advocacy, they have worked with a number of media organizations and advocacy groups. One of these groups is Informed Consent Action Network ("**ICAN**"). ICAN's mission is to disseminate scientific health information to the public. (*See* **Exhibit 2**.) In pursuit of its mission, ICAN relies on its own investigative reporting and the help of institutional whistleblowers and citizen activist, such as de Garays. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free. Most recently, the de Garays were featured on a nearly two-hour long exposé on the HighWire that detailed the full story behind [redacted] participation in the 12-15-Year-Old Pfizer Vaccine clinical trial, her subsequent serious adverse reactions, and the de Garays' attempt to receive support and answers from governmental institutions tasked with the oversight of Pfizer's experimental vaccine.[5]

[3] https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair.

[4] *Id*.

[5] *See* https://thehighwire.com/videos/rigged-maddies-story/.

The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Thus, the de Garays' story will likely be seen by millions of people. Moreover, the de Garays' working relationship with ICAN and the HighWire provides them with the necessary infrastructure to pursue their goals of public advocacy regarding 12-15-Year-Old Pfizer Vaccine, and to widely disseminated any and all records they receive from this FOIA request.

Therefore, between the de Garays' history of public advocacy regarding the 12-15-Year-Old Pfizer Vaccine, and their involvement with media organizations on the issue, regarding the subject of this FOIA request, they are "primarily engaged in disseminating information to the general public." Furthermore, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," here, the data and information underlying the licensure of the 12-15-Year-Old Pfizer Vaccine. Accordingly, expedited processing of this request is warranted.

Recognizing the urgency to inform the public concerning the data and information underlying a licensed vaccine, the Code of Federal Regulations 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…" 21 C.F.R. § 601.51(e) (emphasis added). The FDA's own regulations thus expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* The 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.

This policy is not surprising given the FDA's commitment to transparency and its entire program to assure transparency, because a lack of transparency erodes the confidence the medical and scientific community and the public have in the conclusions reached by the FDA.[6] There is an urgent public need for such transparency with regard to the 12-15-Year-Old Pfizer Vaccine. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the 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" and "effective."[7] 21 C.F.R. 601.2(a). On July 8, 2022, the FDA granted approval to the 12-15-Year-Old Pfizer Vaccine[8] and, beyond the FDA's own regulations which admit the

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

[7] The 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.

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

urgent need for transparency and disclosure in this situation, there are two additional reasons that warrant expedited treatment of this request.

First, there is an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the 12-15-Year-Old Pfizer Vaccine. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, senior editor for The BMJ and associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy,[9] and Peter A. McCullough, professor of medicine at Texas A&M College of Medicine, filed a Citizen Petition[10] with the FDA, claiming that the available evidence for licensure of the Pfizer Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[11] Separately, Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[12] which Peter Marks publicly disputed.[13] Andrew Kheriaty, professor of psychiatry at UCI School of Medicine, Director of the Medical Ethics Program at UCI Health,[14] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[15] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[16] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public[.]"[17]

More recently, a paper published on June 23, 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 COVID-19 vaccine clinical trials are not publicly available. **Given the global public health implications, there is an urgency to make all**

[9] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi.

[10] https://www.regulations.gov/document/FDA-2021-P-0521-0001.

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[17] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf; *See also* https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/.

COVID-19 trial data public, particularly regarding serious adverse events, without any further delay."[18]

Many of these concerns also stem back to FDA's May 10, 2021 reissuance of the Emergency Use Authorization ("EUA") letter of authorization for use of Pfizer-BioNTech's COVID-19 in children ages 12 through 15.[19] These public debates have generated substantial evidence that calls into question the scientific justifications for FDA to issue an EUA for children 12 through 15 when (i) the data does not demonstrate that the known benefits outweigh the known risks and (ii) there are serious concerns regarding how the trials were conducted. These issues have been thoroughly cited and explained in a recent citizen petition filed with the Division of Dockets Management within the Department of Health and Human Services on May 20, 2022.[20] These concerns remain unsettled and part of the national debate. However, with the recent FDA approval of the 12-15-Year-Old Pfizer Vaccine, these concerns have generated even more urgency and importance. Large portions of the public have legitimate fears that FDA never fully demonstrated whether the known benefits outweigh the known risks[21] for this particular age group for the 12-15-Year-Old Pfizer Vaccine, or if the FDA corrected the serious concerns regarding how the 12-15-Year-Old Pfizer Vaccine trials were conducted.

Secondly, now that FDA has approved the 12-15-Year-Old Pfizer Vaccine, there are many indications that states and school districts will begin mandating these vaccines for children to attend public school.[22] Washington, D.C. has already announced a mandate for students ages 12 and older.[23] With legislators, policy makers, and parents deciding how best to protect children as they return to school this fall, there is no more urgent, or appropriate time for the immediate disclosure of the 12-15-Year-Old Pfizer Vaccine's biological product file ("**BLA file**"). The public's value in the release of the BLA file would be significantly diminished if the disclosure is delayed because millions of children, their parents, and their policy makers will be making medical decisions and policies in the coming months. If the disclosure of the BLA file is delayed, many of these children and parents will be forced to make irreversible medical decisions before the independent scientific community, and journalist have time to review, and report upon whether FDA resolved the outstanding concerns regarding its prior EUA when recently approving and licensing the 12-15-Year-Old Pfizer Vaccine.

In light of the above, the de Garays have demonstrated that their request qualifies for expedited processing under FOIA. The de Garays certify that the information in this request is true and correct to the best of their knowledge and belief.

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[18] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239 (emphasis added).

[19] https://www.fda.gov/media/144412/download.

[20] https://www.regulations.gov/document/FDA-2022-P-0872-0001.

[21] https://www.floridahealth.gov/newsroom/2022/03/20220308-FDOH-covid19-vaccination-recommendations-children.pr html.

[22] 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.

[23] *See* https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087.

Fee Waiver Requested

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). The de Garays seek this information to aid in their public advocacy and to assist other organizations who are interested in promoting the public's informed consent of the use of the 12-15-Year-Old Pfizer Vaccine. Thus, we asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the 12-15-Year-Old Pfizer Vaccine and the clinical trials underlying the FDA's approval of same. The information that the de Garays' request will not contribute to any commercial activities.

Note that in the event only a portion or portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. The de Garays reserve all rights to appeal the withholding or deletion of any information.

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If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Exhibit 1

DECLARATION OF PATRICK DE GARAY

STATE OF OHIO

COUNTY OF CLERMONT

I, Patrick de Garay, being duly sworn on oath do say;

1. I am the legal guardian of [redacted] ("[redacted]") de Garay who was born on [redacted]. **Exhibit A – [redacted] de Garay's Birth Certificate**

2. [redacted] was a participant in Pfizer's COVID-19 vaccine clinical trial for 12- to 15-year-olds. **Exhibit B – Proof of [redacted] de Garay's Trial Participation**

3. I have retained legal counsel, Siri & Glimstad LLP ("**Attorney**"), to facilitate the filing, processing, and production of records requests concerning my daughter [redacted] de Garay from the files of any federal health authority, including Health and Human Services ("**HHS**"), National Institutes of Health ("**NIH**"), Food and Drug Administration ("**FDA**"), and Center for Disease Control and Prevention ("**CDC**") pursuant the Freedom of Information Act ("**FOIA**") (5 U.S.C. § 552, as amended).
4. I invoke all the privileges and rights I have as the legal guardian of [redacted] de Garay to obtain the information requested by my Attorney.

5. I authorize the release of records pertaining to a minor: I waive any and all privacy rights afforded to me and [redacted] de Garay that may be implicated by FOIA requests sent by my Attorney, and I consent to the release of all responsive records to my Attorney.
6. I am willing and able to sign any additional forms necessary to authorize the release of records responsive to my Attorney's FOIA requests.

Attachments:
Exhibit A – [redacted] de Garay's Birth Certificate
Exhibit B – Proof of [redacted] de Garay's Trial Participation

Signed 11 day of May 2022
Patrick de Garay
Signature of Patrick de Garay

I, Thomas R Campbell Notary public for the state of Ohio witnessed said Patrick de Garay sign the above statement this 11 day of May 2022.

Notary Public for [signature]

1 of 1

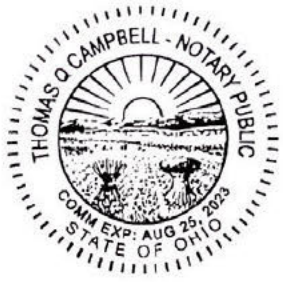

Exhibit A

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF HEALTH
VITAL RECORDS

Certification of Birth

WARNING: IT IS ILLEGAL TO DUPLICATE THIS COPY BY PHOTOSTAT OR PHOTOGRAPH.

DATE OF BIRTH [redacted]

COUNTY OF BIRTH **YORK**

FILE NO [redacted]

DATE FILED [redacted]

DATE ISSUED [redacted]

NAME [redacted] **DE GARAY**

SEX **FEMALE**

FATHER'S NAME

PATRICK KEVIN DE GARAY

MOTHER'S MAIDEN NAME

STEPHANIE CATHARINE HOOK

This is to certify that this is a true copy of the record which is on file in the Pennsylvania Department of Health, in accordance with Act 66, P.L. 304, approved by the General Assembly, June 29, 1953.

Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

Frank Yeropoli
State Registrar

COMMONWEALTH OF PENNSYLVANIA ★ DEPARTMENT OF HEALTH ★

H105 105 1VV Rev 06/06

THE DOCUMENT FACE CONTAINS A YELLOW BACKGROUND AND EMBOSSED SEAL
THE BACK CONTAINS SPECIAL LINES WITH TEXT.

WARNING: THIS DOCUMENT IS PRINTED ON SECURITY WATERMARKED PAPER
DO NOT ACCEPT WITHOUT VERIFYING THE PRESENCE OF THE WATERMARK.

[redacted]

The information appearing on the certified copy of birth is exactly transcribed from information contained on the original birth certificate as filed with the Division of Vital Records.

If you wish to correct the certified copy issued, please complete the lower portion of this form in the presence of a notarizing official.

Mail completed form to: Division of Vital Records
101 South Mercer Street
P.O. Box 1528
New Castle, PA 16101

PLEASE SUBMIT DOCUMENTARY EVIDENCE TO SUPPORT THE CHANGES REQUESTED SUCH AS A COPY OF A BAPTISMAL RECORD, EARLY SCHOOL RECORD, MILITARY RECORD, INSURANCE POLICY OR MARRIAGE LICENSE.

DATA	ORIGINAL RECORD NOW READS	CORRECTIONS DESIRED (print full names, dates, other)
NAME AT BIRTH		
DATE OF BIRTH		
SEX		
OTHER ERROR		
OTHER ERROR		

SEAL

SUBSCRIBED AND SWORN TO BEFORE ME: MO. DAY YEAR

SIGNATURE OF PERSON ADMINISTERING OATH

DO NOT NOTARIZE UNLESS SIGNED BY SUBJECT (OR PARENT(S) IF UNDER AGE 18) MUST BE SIGNED IN PRESENCE OF NOTARY

FATHER'S SIGNATURE

MOTHER'S SIGNATURE

SUBJECT'S SIGNATURE

PRESENT ADDRESS

STREET

CITY STATE ZIP CODE

Exhibit B

COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

De Garay
Last Name

[redacted]
First Name

[redacted]
MI

[redacted]
Date of birth

Patient number *(medical record or IIS record number)*

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19	Pfizer-Covid 19 220395	12/30/20 mm dd yy	CCHMC
2nd Dose COVID-19	Pfizer-Covid 19 220395	01/20/21 mm dd yy	CCHMC
Other		___/___/___ mm dd yy	
Other		___/___/___ mm dd yy	

#secure Pfizer Unblinding Request (Subject Id 1007-1620)

gambleprogram@cchmc.org <gambleprogram@cchmc.org>

Mon 5/17/2021 12:27 PM

To: [redacted]@outlook.com <s[redacted]@outlook.com>

Thank you for your request for unblinding.

We are pleased to inform you that you **received the active Pfizer vaccine** as part of the study. Since you have already received the active COVID-19 vaccine, you do not need to receive another COVID-19 vaccine at this time.

Your study visit schedule will remain the same and we look forward to seeing you at your next study visit. If you would like, we will provide you with your COVID-19 vaccine card at your next visit.

Please respond to this email if you have questions or concerns.

Thank you,

Gamble Vaccine Research Center

Cincinnati Children's Hospital Medical Center
The Gamble Program for Clinical Studies
3333 Burnet Avenue, MLC 6014, Cincinnati, OH 45229
Study Line: 513-636-7699 Fax: 513-636-7682
Email: gambleprogram@cchmc.org

Re: Pfizer e-Diary Follow-up #secure

Stephanie de Garay <[redacted]@outlook.com>
Thu 6/24/2021 12:35 PM
To: idinformatics <idinformatics@cchmc.org>

[redacted] would like to continue with the study, can you please let us know what the activation code is? She has been sick and can't remember what the activation code is.

Thank you

Get Outlook for iOS

From: idinformatics <idinformatics@cchmc.org>
Sent: Thursday, June 24, 2021 11:58:40 AM
To: [redacted]@outlook.com <[redacted]@outlook.com>
Subject: Pfizer e-Diary Follow-up #secure

Dear [redacted] De Garay,

During a recent review of the electronic diary submissions, our data management team noticed that you have not been entering data into the system. Part of the requirement of the COVID-19 vaccine study in which you are enrolled is completion of electronic diaries. We understand that the electronic diary can be difficult and this has been a reason why some people have chosen to discontinue their participation in the study.

Please respond to this email and let us know whether you will be able to re-start entering data into the electronic system or if you would like us to discontinue your participation in the study. If you choose to not respond to this email, we will assume you have opted to discontinue from the study.

If you have questions or would like to speak to the study team, reply to IDInformatics@cchmc.org and we will connect you with the study team.

Sincerely,

The Pfizer COVID-19 Vaccine Study Data Management Team

Participant Updated Notification Booster

[redacted] De Garay

Dear Study Families,

Thank you for your continued participation in the Pfizer COVID-19 Vaccine Study.

On Monday, January 3rd, the FDA approved a booster dose of COVID-19 for people 12 yea above who had their 2nd COVID-19 dose at least 5 months ago. The CDC met with their va advisory board on Wednesday, January 5th to review the FDA approval and presented gui booster dose for 12-15 year olds. Now that these steps have taken place, we can begin to booster doses as part of the study.

Over the next couple of weeks, we will be preparing the study materials in order to begin booster doses for eligible participants. In the meantime, we have 4 options for you and y consider:

Option 1: Continue in the current study and receive a 30 mcg booster dose to anyor age or older as long as it has been at least 6 months since the 2nd dose.

Option 2: Participants ≥ 12 may participate in a sub-study that will evaluate a boos 10 mcg verses a booster dose of 30 mcg. We know that children 5-11 years old giver dose of vaccine have the same amount of antibody as 16-25 year olds who get a 30 So, we believe a 10 mcg booster in 12-15 olds will produce immunity with less side

Option 3: Participants 12 to 30 years old may participate in a sub-study that looks developing myocarditis after receiving a 30mcg booster dose.

Option 4: Withdraw from the study and receive a booster dose in the community.

Choice:

* must provide value

- ○ Option 1: Continue in the current study and receive a booster
- ○ Option 2 or Option 3: Interested in Sub-studies
- ○ Option 4: Withdraw from the study and receive a booster dose in the community.
- ○ No choice: Comment to study team in lieu of choosing an option

Submit

Save & Return Later

Exhibit 2

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022

Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed said Catharine Layton sign the above statement this 3 day of May (month), 2022

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024

Exhibit 8

U.S. FOOD & DRUG ADMINISTRATION

August 29, 2022

SIRI & GLIMSTAD LLP
AARON SIRI
745 Fifth Ave.
New York NY 10151 US

In Reply refer to
FOIA Control #:
2022-6129

Requester reference:
IR#0832

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information 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.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

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. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Public Health and Medical Professionals for Transparency, and Patrick and Stephanie de Garay

(b) County of Residence of First Listed Plaintiff Tarrant
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Siri and Glimstad LLP 501 Congress Ave. Suite 150 - #343, Austin TX 78701, 512-265-5622

DEFENDANTS

Food and Drug Administration

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☒ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

- ☐ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331

Brief description of cause:
Freedom of Information Act, 5 U.S.C. § 552

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Mark T. Pittman DOCKET NUMBER 4:21-cv-01058-P

DATE
Oct 11, 2022

SIGNATURE OF ATTORNEY OF RECORD
/s/ Walker D. Moller

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related cases, if any. If a related case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is related to this filing if the case: 1) involves some or all of the same parties and is based on the same or similar claim; 2) involves the same property, transaction, or event; 3) involves substantially similar issues of law and fact; and/or 4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.

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

RULE 7.1 STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1 and to enable District Judges and Magistrate Judges of the Court to evaluate possible disqualification or recusal, the undersigned counsel for PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY (a private non-governmental party) and PATRICK AND STEPHANIE DE GARAY certifies that the following are corporate parents, affiliates and/or subsidiaries of said party, which are publicly held.

None.

Dated: October 11, 2022

SIRI & GLIMSTAD LLP

Aaron Siri (*pro hac vice* to be filed)
Elizabeth A. Brehm (*pro hac vice* to be filed)
Colin Farnsworth (*pro hac vice* to be filed)
745 Fifth Ave, Suite 500
New York, NY 10151
Tel: (212) 532-1091
aaron@sirillp.com
ebrehm@sirillp.com
cfarnsworth@sirillp.com

/s/ Walker D. Moller
Walker D. Moller (Texas Bar No. 24092851)
501 Congress Avenue, Suite 150 – #343
Austin, TX 78701
Tel : (512) 265-5622
wmoller@sirillp.com

Attorneys for Plaintiffs