Exhibit 5

Siri | Glimstad

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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.