

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL

August 27, 2021

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

Re: Pfizer-BioNTech COVID-19 Vaccine Biological Product File (IR#0546)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency (“PHMPT”).

On August 23, 2021, the Food and Drug Administration (“FDA”) approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty (the “**Pfizer Vaccine**”) for individuals 16 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 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 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.

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)(II). When the person requesting information is “primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity” constitutes a “compelling need” for expedited processing. 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 Government activity,” here, the data and information underlying the licensure of the Pfizer Vaccine. Accordingly, expedited processing of this request is warranted.

³ See, e.g., <https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role> (Harvey Risch) (last visited 8/26/2021)

⁴ See, e.g., <https://www.bmj.com/content/373/bmj.n1244> (Peter Doshi) (last visited 8/27/2021); <https://www.bmj.com/content/371/bmj.m4058> (Peter Doshi) (last visited 8/27/2021); <https://www.bmj.com/content/371/bmj.m4037> (Peter Doshi) (last visited 8/27/2021); <https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749> (last visited 8/25/2021); <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (Aaron Kheriaty and Gerard V. Bradley) (last visited 8/27/2021); <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) (last visited 8/27/2021); <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) (last visited 8/27/2021); <https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf> (Serena Tinari and Catherine Riva) (last visited 8/27/2021); <https://www.bmj.com/content/372/bmj.n627> (Serena Tinari) (last visited 8/27/2021); <https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735> (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi) (last visited 8/27/2021); <https://www.arcdigital.media/p/medical-ethicist-sues-the-university> (Justin Lee) (last visited 8/27/2021).

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) (last visited 8/27/2021); <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) (last visited 8/27/2021). See also <https://www.re-check.ch/wordpress/en/covid-certificate/> (Catherine Riva and Serena Tinari) (last visited 8/27/2021).

⁶ See <https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/> (Andrew Bostom) (last visited 8/27/2021).

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) (last visited 8/27/2021).

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 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 August 23, 2021, the FDA granted approval to the Pfizer Vaccine¹⁰ 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 Pfizer 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 Pfizer Vaccine is more than sufficient for licensure. For example, in a press release issued on August 23, 2021, acting FDA Commissioner Janet Woodcock stated that “the public can be very confident that [the Pfizer Vaccine] meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product.”¹¹ Peter Marks, the director of FDA’s Center for Biologics Evaluation and Research, made similar remarks, stating that

[The FDA’s] scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of [the Pfizer Vaccine]. We

⁸ <https://www.fda.gov/about-fda/transparency> (last visited 8/27/2021).

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> (last visited 8/27/2021). *See also* <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> (last visited 8/27/2021); <https://www.fda.gov/about-fda/what-we-do> (last visited 8/27/2021).

¹⁰ *See* <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 8/27/2021). *See also* <https://www.cnn.com/2021/08/23/health/fda-approval-pfizer-covid-vaccine/index.html> (last visited 8/27/2021). The Washington Post claims that approval of the Pfizer Vaccine was the “fastest in the agency’s history.” <https://www.washingtonpost.com/health/2021/08/23/pfizer-vaccine-full-approval/> (last visited 8/27/2021).

¹¹ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited 8/27/2021).

evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of [the Pfizer Vaccine’s] safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities[.]¹²

Peter Marks further stated that “although [the FDA] approved [the Pfizer Vaccine] expeditiously, it was fully in keeping with [the FDA’s] existing high standards for vaccines in the U.S.”¹³ President Biden also stated that the FDA’s approval meets the “gold standard.”¹⁴ Even prior to FDA approval of the Pfizer Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines are “safe and effective.”¹⁵

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 Pfizer Vaccine, including a number of the scientists and journalists that are members of PHMPT. 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,¹⁶ and Peter A. McCullough, professor of medicine at Texas A&M College of Medicine, filed a Citizen Petition¹⁷ 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.”¹⁸ Separately, Peter Doshi has publicly questioned the lack of transparency regarding the vaccine approval process¹⁹ which Peter Marks publicly disputed.²⁰ Andrew Kheriaty, professor of psychiatry at UCI

¹² *Id.*

¹³ *Id.*

¹⁴ <https://www.cbsnews.com/news/biden-address-covid-19-vaccine-pfizer-fda-approval-watch-live-stream-today-2021-08-23/> (last visited 8/27/2021).

¹⁵ 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 8/27/2021). 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 8/27/2021); <https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness> (“COVID-19 vaccines are safe”) (last visited 8/27/2021); <https://www.wlns.com/news/gov-whitmer-and-dr-khaldun-respond-to-the-fda-approval-of-pfizers-covid-19-vaccine/> (quoting Governor Whitmer referring to the Pfizer Vaccine as a “safe, effective COVID-19 vaccine”) (last visited 8/27/2021).

¹⁶ <https://www.bmj.com/about-bmj/editorial-staff/peter-doshi> (last visited 8/27/2021).

¹⁷ <https://www.regulations.gov/document/FDA-2021-P-0521-0001> (last visited 8/27/2021).

¹⁸ 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 8/27/2021).

¹⁹ 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 8/27/2021); <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 8/27/2021); <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 8/27/2021).

²⁰ <https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/> (last visited 8/27/2021).

School of Medicine, Director of the Medical Ethics Program at UCI Health,²¹ 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 review²² by the FDA’s Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.²³ 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[.]”²⁴ 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 Pfizer Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific community and the public has an immediate need to review the data and information underlying the licensure of the Pfizer 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 Pfizer Vaccine. The FDA should produce the data and information necessary to address this widespread public debate by immediately producing the information requested in this FOIA request.

There is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the Pfizer Vaccine because, over the objections of many, this product is being mandated to individuals across the country by the federal government,²⁵ local

²¹ <https://www.aaronkheriaty.com/bio> (last visited 8/27/2021).

²² <https://www.fda.gov/media/150054/download> (last visited 8/27/2021).

²³ <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (last visited 8/27/2021).

²⁴ https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 8/27/2021). *See also* <https://www.washingtontimes.com/news/2021/aug/23/editorial-the-coincidental-timing-of-pfizers-vacci/> (last visited 8/27/2021).

²⁵ *See, e.g.,* <https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1> (last visited 8/27/2021); <https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c> (last visited 8/27/2021); <https://www.forbes.com/sites/joewalsh/2021/08/09/us-military-will-require-covid-vaccinations-by-mid-september/?sh=78defacd6c9f> (last visited 8/27/2021); <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 8/27/2021).

governments,²⁶ public and private employers,²⁷ universities,²⁸ schools,²⁹ and various other institutions,³⁰ and many are expected to follow suit.³¹ At the federal level, legislation was recently introduced that would require COVID-19 vaccines for air travel into or out of the United States³² and the Pentagon has mandated the COVID-19 vaccines for all military personnel.³³ At the state

²⁶ See, e.g., <https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html> (last visited 8/27/2021); <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page> (last visited 8/27/2021); <https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html> (last visited 8/27/2021).

²⁷ See, e.g., <https://www.cnn.com/2021/08/06/united-airlines-vaccine-mandate-employees.html> (last visited 8/27/2021); <https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/> (last visited 8/27/2021); <https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220> (last visited 8/27/2021); <https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/> (last visited 8/27/2021); <https://www.cnn.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html> (last visited 8/27/2021); <https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/> (last visited 8/27/2021); <https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates> (last visited 8/27/2021); <https://cvshhealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees> (last visited 8/27/2021).

²⁸ See <https://universitybusiness.com/state-by-state-look-at-colleges-requiring-vaccines/> (last visited 8/27/2021). See also, e.g., <https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916> (last visited 8/27/2021); <https://www.colorado.edu/covid-19-updates/covid-19-vaccination> (last visited 8/27/2021); <https://uhs.berkeley.edu/requirements/covid19> (last visited 8/27/2021); <https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs> (last visited 8/27/2021); <https://www2.gmu.edu/safe-return-campus/vaccination-requirements> (last visited 8/27/2021); <https://www.pc.pitt.edu/news/vaccine-disclosure-requirements-2021-2022-campus-housing> (last visited 8/27/2021).

²⁹ 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 8/27/2021); <https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band> (last visited 8/27/2021); <https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/> (last visited 8/27/2021); <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 8/27/2021); <https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/> (last visited 8/27/2021).

³⁰ 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 8/27/2021); <https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/> (last visited 8/27/2021); <https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html> (last visited 8/27/2021); <https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers> (last visited 8/27/2021); <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx> (last visited 8/27/2021); <https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html> (last visited 8/27/2021); <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 8/27/2021); See <https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/> (last visited 8/27/2021).

³¹ See <https://www.mississippifreepress.org/15126/fda-fully-approves-pfizer-biontech-vaccine-mandates-to-follow/> (last visited 8/27/2021); https://www.huffpost.com/entry/vaccine-mandates-roll-out-fda-approval_n_6123e028e4b0df3eacd5d657 (last visited 8/27/2021); https://www.theadvocate.com/baton_rouge/news/coronavirus/article_9be6d02c-0434-11ec-b7b1-cb17d8495274.html?utm_medium=social&utm_source=twitternoladotcom&utm_campaign=snd (last visited 8/27/2021). See also <https://www.latimes.com/california/story/2021-08-26/california-lawmakers-grapple-with-statewide-covid-19-vaccine-mandate> (last visited 8/27/2021).

³² <https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%2522> (last visited 8/23/2021).

³³ <https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military> (last visited 8/23/2021).

level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,³⁴ all state employees,³⁵ and even for all citizens of the state.³⁶ As explained by Dr. Anthony Fauci, “a flood” of vaccine mandates will follow FDA approval of a COVID-19 vaccine³⁷ and President Biden is actively encouraging “companies in the private sector to step up the vaccine requirements[.]”³⁸ 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 Pfizer 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. 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 mandated or potential mandates of the Pfizer Vaccine.

PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

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 Pfizer 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 if only 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

³⁴ See New York bill S6495 available at <https://www.nysenate.gov/legislation/bills/2021/S6495> (last visited 8/27/2021).

³⁵ 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 8/27/2021).

³⁶ 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 8/27/2021).

³⁷ <https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/> (last visited 8/27/2021).

³⁸ <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-AAANeYs?ocid=uxbndlbing> (last visited 8/27/2021). 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 8/23/2021); <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-AAANGDTy?ocid=uxbndlbing> (last visited 8/23/2021); <https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html> (quoting the Surgeon General referring to vaccine mandates as “reasonable”) (last visited 8/23/2021).

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

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