UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

BRIEF IN SUPPORT OF TIMELY PRODUCTION

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Plaintiff, Public Health and Medical Professionals for Transparency ("**PHMPT**"), by and through its attorneys, Siri & Glimstad LLP, respectfully submits this brief in support of prompt and timely production of the documents submitted by Pfizer Inc. ("**Pfizer**") to the U.S. Food and Drug Administration (the "**FDA**") to license its COVID-19 vaccine (the "**Pfizer vaccine**").

PRELIMINARY STATEMENT

A minimum of 20,010 days (54 years and 10 months). That is how long the FDA proposes to take, at a rate of 500 pages per month, to produce only a portion of the documents in its file for the COVID-19 Pfizer vaccine that PHMPT requested pursuant to the Freedom of Information Act (the "**FOIA Request**") and 21 C.F.R. § 601.51(e). But when it came to reviewing those same documents to license this product so that Pfizer could freely sell it to the public, the FDA took **just 108 days**. It took the FDA's parent department even less time to grant Pfizer complete immunity to liability for injuries from this product, and it took a stroke of the President's pen to mandate this product for federal employees, the private sector and military personnel.

The federal government mandating that millions of people be injected with a liability-free vaccine requires complete government transparency – not the government's suppression of information. PHMPT is comprised of independent scientists working at some of our nation's premier institutions, and all they are seeking is the data the FDA has already reviewed concerning the Pfizer vaccine in order to provide the necessary peer review. The FDA knows that they, and other independent scientists, cannot properly analyze that data until it is all released. Yet, the FDA wants to wait until most of those scientists are long since dead to fully release the data. News outlets, politicians, and scientists have called the FDA's position "outrageous." They are correct.

The entire purpose of FOIA is government transparency. In multiple recent cases, in upholding the FOIA's requirement to "make the records promptly available," courts have required

agencies, including the FDA, to produce 10,000 or more pages per month, and those cases did not involve a request nearly this important – *i.e.*, the data underlying licensure of a liability-free product that the federal government requires nearly all Americans to receive. As the present pandemic rages on, independent review of these documents by outside scientists is urgently needed to assist with addressing the shortcomings and issues with the response to the pandemic to date.

The context surrounding PHMPT's FOIA request is truly unprecedented, and the request should be treated as such. Historically, there has been no consumer product that the federal government has mandated Americans to receive. Now, it has mandated Pfizer's vaccine to private sector employees, federal employees, the military, and more. States have done the same at the urging of the federal government, extending mandates for people to enter schools, universities, restaurants, and public venues, among other places. A majority of Americans are now mandated to receive this product under penalty of losing a job or worse. This is truly unparalleled in the nation's past. There has never been such a large-scale mandate of any product for society, let alone one that is injected into people. Even school mandates under state laws have almost always included an easy to obtain exemption. The current inability to say "no" to injecting a product into one's body absent serious consequences dictated by the government is truly unprecedented.

Making this even more unprecedented is that Americans, if injured, cannot sue Pfizer and otherwise have no recourse. There is virtually no other product where a consumer is prohibited from suing the company that manufactures, markets, and profits from the product. Decoupling a company's profit interest from its interest in safety is a moral hazard, and a departure from centuries of product liability doctrine. Yet we find ourselves in this truly extraordinary circumstance where not only must Americans take this product under penalty of expulsion from work, school, the military and civil life, but they cannot sue Pfizer for any resulting injuries.

And who has created this unprecedented situation? The Executive Branch, normally with little or no input from the other branches. It has granted the immunity, licensed the product, and aggressively implemented or demanded mandates. This therefore requires *unprecedented* transparency. When Americans cannot say "no" and cannot sue Pfizer for harm, then the FDA should also not be able to say "no" to forthwith releasing the Pfizer vaccine data. If the administration wants Americans to be subject to its mandates, Americans must at least be granted the dignity of access to the data supposedly supporting the safety and efficacy of Pfizer's liability-free vaccine so that independent scientists can conduct a timely review.

Even President Joe Biden, when truth was original to him as candidate Joe Biden, on January 28, 2020, told the American people that, "**You've got to make all of it [the vaccine data] available to other experts across the nation so they can look and see, so there's a consensus this is a safe vaccine**." (App000338 ¶ 2.) On September 7, 2020, on national television, he stated:

> I get asked the question, if … President [Trump] announced tomorrow we have a vaccine, would you take it? **Only if it was completely transparent and other experts in the country could look at it**. **Only if we knew all of what went into it.**

(App000338 ¶ 3.) And then he again said to the American people that we need "**total transparency so scientists outside the government know exactly what is being approved**." (App000339 ¶ 4.) Fifteen U.S. Senators, all caucusing Democrats, similarly stated as follows in a letter to the FDA:

> **Full transparency throughout the review and authorization process is thus essential to countering real or perceived politicization and building public confidence in any approved vaccine**. … In addition to the efforts FDA has already made to publish its recommendations regarding data needed for clinical development and licensure of vaccines, **a transparent review process will require that FDA … make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public**.

(App000339 ¶ 8.) Numerous Republicans have also demanded immediate release of the documents. For example, Congressman Ralph Norman recently stated:

> The FDA's only priority should be the health and safety of consumers. The agency has compromised its integrity by delaying information that belongs to the public. Since the Biden administration is hell-bent on forcing these vaccine mandates on us, the public has every right to know how this vaccine was approved, especially in such a short amount of time. After all, the FDA managed to consider all 329,000 pages of data and grant emergency approval of the Pfizer vaccine within just 108 days. So it's hard to rationalize why it now needs 55 years to fully release that information to the public.

(App000339 ¶ 9.) Senator Ted Cruz called the FDA's position "Completely outrageous." (App000340 ¶ 10.)

The transparency sought by politicians is consistent with well-established norms in the scientific community and with the purpose of FOIA; but that purpose will be utterly frustrated unless the data is released now**, in its entirety**, to the public. Releasing this data, so independent scientists can review it, is akin to getting a second opinion from a doctor, or a peer review of a scientific paper. Every day that passes without this data's release is another day that the American people are deprived of this basic transparency and review.

The FDA does not dispute that it should produce these documents. Rather, it proposes doing so at a rate so slow that the documents will not be fully produced until almost all of the scientists, attorneys, and most of the Americans that received Pfizer's product, will have died of old age. The FDA's excuse? It cries it does not have the resources. Considering how many taxpayer dollars this administration has spent on its COVID-19 response, the FDA cannot now claim it lacks the money to timely conduct its review. This excuse is a red herring that just adds insult to the liberty-crushing approach the FDA and administration have taken with this product.

The Executive Branch gave Pfizer $1.95 billion in taxpayer funds to promote development of its vaccine through an advance-purchase agreement. (App000340 ¶ 11.) It then paid Pfizer more than $15.7 billion collected from the American people to purchase that product. (App000340-App000341 ¶¶ 12-16.) Thereafter, it spent $18.75 billion more of the American people's money promoting that product. (App000341 ¶¶ 17-19.) Yet, when it comes to being transparent with those same American people, the FDA claims it cannot muster the resources to timely produce the same documents it reviewed for licensure in 108 days. Just as the government found the resources for Operation Warp Speed, it must now do the same to produce these critical documents with the same warp speed. How about the federal government spend just 0.1% of the taxpayer money it has given Pfizer – that would be at least $17.6 million – a pittance compared to the billions given to Pfizer and more than sufficient to hire enough reviewers to timely produce the documents. Companies in private litigation produce hundreds of thousands of pages per month in discovery, reviewing each document for privilege, etc. But yet the vast federal government, on an issue this important, claims it cannot find the resources. A product the administration says everyone must take under penalty of exclusion from American life and for which they cannot even sue Pfizer if injured! Whose interests is the executive branch protecting, the American people or its own?

Reflecting that the FDA can, in fact, produce documents at a far greater rate than 500 pages per month, on December 1, 2021, in an effort to avoid the hearing with this Court, it offered to produce approximately 12,658 pages, 4 .txt files, and 4 SAS files within a period of 61 days if PHMPT would agree to thereafter only receive 500 pages per month. (App000341 ¶ 20.) The FDA does not appear to recognize the gravity of its ethical breach to the American people in playing these games.

The pandemic is continuing to spiral. Despite over 83% of adults having received a COVID-19 vaccine (App000341 ¶ 21), **cases are on the rise in the most vaccinated states** (App000342 ¶ 22), **variants that evade vaccine immunity are rising** (App000342 ¶ 24), **the CDC has admitted the COVID-19 vaccines do not prevent transmission** (App000342 ¶ 23), **the number of breakthrough cases is increasing exponentially** (App000342 ¶ 25), **and boosters are now needed for everyone and will likely continue to be required every six months, if not more frequently** (App000342 ¶ 26), among numerous other issues with the vaccine program.

America has some of the greatest institutions of learning and research the world has ever known. We need all these hands on deck, both inside and outside the government, to address these serious, ongoing issues, and failings within the vaccine program. Locking out independent scientists from addressing these issues is dangerous, irresponsible, and unethical. The FDA, in both the prior and current administration, has never been free of political pressure when conducing its work and it has also been widely promoting this vaccine to the public, including before it was licensed. This all raises questions about the licensure process and whether the FDA will admit mistakes or failings of the same product, mistakes and failings that will only be identified through outside review. America needs independent scientists, like the ones from our premier universities and medical centers comprising Plaintiff, to review this data and assist with offering solutions and addressing these issues. Not 55 years from now or longer. **But today.**

BACKGROUND

A. The Need for the Transparency as Promised by Pfizer, White House, and FDA

Pfizer itself acknowledges the need for "Transparency in Clinical Trials." (App000342 ¶ 27 (Pfizer's policy statement from December 2019 explaining its "commitment to openness and transparency" including in "all aspects of research and development behind our products, including clinical trials."). *See also* App000342 – App000343 ¶ 28.) Similarly, the U.S Institute of Medicine

consensus study emphasized "that verification and replication of investigators claims [in clinical trials] were essential to the scientific process" and results in "numerous benefits to … patients, their physicians and researchers." (*Id.* (internal quotations eliminated).)

Likewise, as quoted *supra*, numerous U.S. Representatives and Senators, and the White House and FDA leadership, have all called for transparency; as Presidential candidate Joe Biden, told the American people: "You've got to make all of it [the vaccine data] available to other experts across the nation so they can look and see." (App000338 – App000340 ¶¶ 2-4, 8-10.)

These call for transparency is consistent with well-established norms in the scientific community. As explained by a PHMPT member who is also a member of the World Health Organization's COVID-19 Infection Prevention and Control Working Group:

> The importance of independent review of data in science cannot be overstated. Science is never static. … Censorship and lack of transparency have always been the enemies of progress. … Given the insufficient and hurried testing and the culture of secrecy, it is arguable whether any informed consent is valid prior to making public all of the documents the FDA has in Pfizer's COVID-19 file.

(App000108 ¶ 17.) As explained by another PHMPT member, a full professor of epidemiology at Yale School of Public Health and Yale School of Medicine, Dr. Harvey Reich: "Absent an independent review, the nation is dependent on one body's review," that of the FDA. (App000008 ¶ 10.) He explains this is concerning because the FDA was "under tremendous political pressure [to license the Pfizer vaccine], which shortened the typical review process, making it impossible to carry out all analyses that are typically carried out." (*Id.*) Hence, he continues, "[a]llowing the Pfizer vaccine data to be made available to independent scientists and healthcare professionals is akin to a peer review process and is critical to ensure the accuracy of the conclusions reached." (App000009 ¶ 12.)

Dr. Reich continues that: "Independent scientists and epidemiologist … need this data

sooner rather than later… We are still in a pandemic, the vaccines are failing, children are starting to be vaccinated, we are moving to boosters for all eligible Americans and so we need to have as complete an understanding of these vaccines and their efficacy, or lack thereof, as soon as possible so that we can learn how to properly manage things moving forward… Time is of the essence. Collective efforts of all scientists in the United States will produce more insights at a quicker pace than if the FDA hoards data, prohibiting others from getting involved." (App000011 ¶ 16.)

B. PHMPT Formed to Disseminate the Promised Vaccine Data

PHMPT is a not-for-profit with more than 75 members, including professors at major universities, public health professionals, medical doctors, scientists, and journalists, and current and former WHO and HHS COVID-19 advisory group members. (App000002 ¶ 3.)

PHMPT exists for the sole purpose of making public the data in the biological product files for each licensed COVID-19 vaccine. (App000003 ¶ 5.) Many of its members, who include journalists, are primarily engaged in disseminating information to the public. (App000002 ¶ 4.) Through its members and website, PHMPT intends to disseminate to the public all records it receives. (App000003 ¶ 7.)

C. FDA Approval of the Pfizer Vaccine

On August 23, 2021, the FDA approved the Pfizer vaccine. (App000343 ¶ 29). Despite the promise of transparency, not a single page submitted by Pfizer to the FDA was released to the public. (App.000008 ¶ 10.) This is hindering the nation's response to the pandemic and, as President Biden and others predicted, has led to skepticism regarding this product.

On the one hand, prominent figures in the media, politics, and public health fields have sought to reassure the public that the data evaluated by the FDA was sufficient for licensure. For example, Dr. Peter Marks, the Director of FDA's biologics/vaccine division stated that

> [the FDA's] scientific and medical experts conducted an incredibly

> thorough and thoughtful evaluation of [the Pfizer vaccine]. We 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[.]

(App000343 ¶ 29.). Dr. 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." (*Id.*)

On the other hand, numerous prominent scientists have questioned the sufficiency of the data submitted by Pfizer and the adequacy of the FDA's review to license its vaccine. For example, on June 1, 2021, a group of 27 clinicians and scientists, including professors from Harvard Medical School, and members of PHMPT, filed a Citizen Petition 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." (App000343 ¶¶ 30-31.) Similarly, Professor Peter Doshi, a senior editor at The British Medical Journal and a PHMPT member, has publicly questioned the adequacy of the data the FDA relied on for licensure and the lack of transparency in the vaccine approval process. (App000343 ¶¶ 32-33.)

Incredibly, the FDA even denied the public the opportunity to hear discussion about the data and to offer public comment by not convening its public advisory committee, the Vaccines and Related Biological Products Advisory Committee, to discuss licensure. (App000343 ¶ 34.)

D. <u>Mandates Abound While the FDA Hides the Data</u>

While hiding Pfizer's data from the public, the federal executive has pushed an agenda to make it impossible to participate in American society without receiving the Pfizer vaccine. This includes mandates by the federal executive for private sector employees, public sector employees, health care professionals, federal contractor employees, military personnel, and certain air

travelers. (*See, e.g.*, App000344 ¶¶ 35-37.) Mandates have also been instituted by state and local governments at the urging of the federal government on university students, customers at retail stores, diners at restaurants, and virtually dozens of other everyday locations visited in the normal affairs of American life. (*See, e.g.*, App000344 ¶¶ 38-39.) Many more are expected to follow suit. (*See, e.g.*, App000344 – App000345 ¶ 40.)

Some mandates now require three doses of Pfizer's vaccine, and the number of doses Americans must receive to simply keep their job and otherwise engage in civil society is only expected to increase over time. (App000342 ¶ 26.) What makes this all the more incredible is that Pfizer's vaccine does not prevent infection and transmission. (App000342 ¶ 23.) Meaning, at best, Pfizer's vaccine provides personal protection, akin to taking statins. We may want people to take their heart medicine, but we don't mandate them to do so. That is simply authoritarian.

E. <u>If the Above Is Not Enough, the Federal Government Granted Pfizer Immunity</u>

While hiding Pfizer's data from the public, the federal government granted Pfizer, and anyone associated with administering its vaccine, complete legal immunity for any injury caused by its vaccine. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to … prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to all claims … resulting from … [its] use by an individual"). Pfizer is even immune from liability for willful misconduct unless the federal government, which promoted and licensed this product, first brings this claim. *Id.* So, to be clear, Americans are forced to receive Pfizer's product, but if injured, they cannot sue anyone associated with this vaccine, yet the government is refusing to permit outside scientists to review the data supporting its safety.

F. <u>PHMPT's FOIA Request</u>

On August 27, 2021, just four days after the FDA approved the Pfizer vaccine, PHMPT submitted the FOIA Request to the agency, seeking the following documents:

> All data and information 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.

(App000345 ¶ 41.) 21 C.F.R. § 601.51(e) lists the "data and information in the biological product file" that is supposed to be "**immediately available for public disclosure**" after the FDA licenses a vaccine. (emphasis added). That data and information includes, *inter alia*, "[a]ll safety and effectiveness data and information[,]" "[a] protocol for a test or study" of the vaccine, "[a]dverse reaction reports," and "[a]ll correspondence and written summaries of oral discussions relating to the biological product file[.]" 21 C.F.R. § 601.51(e)(1)-(8). On August 31, 2021, the FDA assigned the FOIA Request case number 2021-5683. (App000345 ¶ 43.)

As part of its FOIA request, PHMPT requested expedited professing pursuant to 5 U.S.C. § 552 (a) (6)(E)(v)(II). On September 9, 2021, the FDA denied PHMPT's request (the "**Denial Letter**"). In the Denial Letter, the 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. (App000345 ¶ 44).

G. FDA Proposes to Process the Documents Over the Next 55-plus Years

On November 15, 2021, the parties submitted a Second Joint Report to the Court. (Dkt. No. 20.) Therein, the FDA reported "that there are more than 329,000 pages potentially responsive to Plaintiff's FOIA request." (*Id.* at p. 3.) This page count does not include other files, "typically containing data in a format similar to a spreadsheet." (*Id.*). In order to produce those responsive documents, the "FDA propose[d] to process and produce the non-exempt portions of responsive records at a rate of 500 pages per month." (*Id.* at p. 4.) At that rate, it will take the FDA at least **54 years and 10 months** to produce all the responsive documents – not exactly meeting the FOIA

statute's requirement that the agency "shall make the records promptly available." 5 U.S.C. § 552(a)(3)(A). The FDA's proposed schedule is tantamount to a denial of the FOIA Request.

PHMPT therefore asked the Court to direct the FDA to produce all responsive documents by no later than March 3, 2022. (Dkt. No. 20 p. 9.) "This 108-day period [from the date the Joint Report was filed] is the same amount of time it took the FDA to review the responsive documents for the far more intricate task of licensing Pfizer's Covid-19 vaccine." (*Id.*) In response, the Court ordered a scheduling conference for December 14, 2021, and directed the parties to file briefs or appendices that could "assist the Court in its preparation for the" conference. (Dkt. No. 21.)

In the more than three months since PHMPT submitted the FOIA request, the FDA has produced only an index of documents, 1 txt file, 1 xpt file, and 339 pages of information, most of which concerned the principal investigators for the Pfizer vaccine trials, information that was already publicly available on the clinicaltrials.gov website. Counsel for the FDA has also recently advised PHMPT's counsel that in addition to the 329,000+ pages, there are an additional "approximately 39,000 pages" plus "ten of thousands of additional pages" plus hundreds of spreadsheets and the FDA will treat each twenty lines in each spreadsheet as one page. (App000345 ¶ 45.) Meaning, the FDA's position is that the independents scientists can review the data but they will just have to wait until long after they are all dead.

ARGUMENT

I. THE REQUEST QUALIFIES FOR EXPEDITED REVIEW AND PRODUCTION

"The FOIA was enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir 2010) (quoting *Dep't of the Air Force v. Rose,* 425 U.S. 352, 361 (1976)). And courts have long acknowledged that "'stale information' produced pursuant to FOIA requests 'is of little value.'" *Huddleston v. Fed. Bur. of Investigation*, No. 4:20-CV-447, 2021 WL 327510, at *3 (E.D. Tex.

Feb. 1, 2021) (quoting *Payne Enterprises v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)). *See also Open Soc'y.*, 399 F. Supp. 3d at 164 ("Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" (*quoting* H.R. Rep. No. 93-876, at 6271 (1974)). That is why Congress amended the FOIA statute in 1996 to mandate expedited processing of important FOIA requests.

Here, PHMPT is unquestionably entitled to the information sought in the FOIA Request because the FDA's own regulations require the information to be "immediately available" to the public. 21 C.F.R. § 601.51(e). *See also Pub. Citizen Health Research Group v. F.D.A.*, 964 F. Supp. 413, 414 (D.D.C. 1997) (finding that data submitted for drug licensure had to be disclosed under FOIA because "[o]nce an approval letter has been sent, certain data and information are immediately available for disclosure"). The question is how quickly the FDA will produce those documents. Given the clear national importance, this Court should direct that all responsive documents be produced within 108 days of November 15, 2021.

1. The Standard For Reviewing Requests to Expedite

FOIA provides for "expedited processing of request for records" when there is a "compelling need." 5 U.S.C. § 552 (a)(6)(E). The statute states that a compelling need includes: "**with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity**." *Bloomberg, L.P. v. United States Food and Drug Admin.*, 500 F. Supp. 2d 371, 376-77 (S.D.N.Y. 2007) (quoting 5 U.S.C. § 552 (a)(6)(E)(v)); *Citizens for Responsibility and Ethics in Washington v. U.S. Dept. of Justice*, 436 F. Supp. 3d 354, 358 (D.D.C. 2020) (applying the same standard). The FDA's regulations contain the same definition of when a compelling need exists. 21 C.F.R. § 20.44 (a). "'Unlike the review of other agency action that must be upheld if supported by

substantial evidence and not arbitrary or capricious, the FOIA expressly places the burden on the agency to sustain its action and directs the district courts to determine the matter de novo.'" *Avondale Indus., Inc. v. N.L.R.B.*, 90 F.3d 955, 958 (5th Cir. 1996) (quoting *United States Dept. of Justice v. Reporters Committee*, 489 U.S. 749, 755 (1989)). *See also Bloomberg, L.P.*, 500 F. Supp. 2d at 374 ("The Court reviews agency decisions, including those regarding expedited processing of FOIA requests, *de novo.*").

2. PHMPT's Request Must be Expedited

There is no question PHMPT is "primarily engaged in disseminating information" because, as explained on its website, it "exists solely to obtain and disseminate the data relied upon by the FDA to license COVID-19 vaccines" and that "[a]ny data received will be made public on this website." (App000003 ¶¶ 5, 7.) *See also Bloomberg, L.P.*, 500 F. Supp. 2d at 378 (holding that the "inability of the general public to understand the raw data submitted by the drug manufacturers" has no bearing on the urgent need to produce that data).

As for showing an "urgency to inform the public concerning actual or alleged Federal Government activity," PHMPT's request easily meets this standard. 5 U.S.C. § 552 (a)(6)(E)(v). In answering this question, "[c]ourts must consider at least the following three factors …: (1) 'whether the request concerns a matter of exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.'" *Bloomberg, L.P.*, 500 F. Supp. 2d at 377 (quoting *Al-Fayed v. C.I.A.*, 254 F.3d 300, 310 (D.C. Cir. 2001)). The FDA's FOIA regulations present a similar tripartite analysis, and ask whether: (1) "[t]here is an urgent need for the requested information[,]" (2) the information "has a particular value that will be lost if not obtained and disseminated quickly[,]" and (3) "[t]he request … specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(2)-(3). PHMPT's FOIA

Request satisfies both of these tests.

i. Urgent Need for Independent Review of Pfizer Vaccine Data

Independent review of Pfizer's vaccine data is a matter of current "exigency to the American public." *Bloomberg, L.P.*, 500 F. Supp. 2d at 377. There can be no question that the FDA's approval of Pfizer's vaccine, and its safety and efficacy, is one of the most covered news stories of the last decade. The need for rapid independent review of the data Pfizer submitted to the FDA is central to this story, and disseminating this data is PHMPT's *raison d'etre*.

As discussed above, there exists unanimity from all quarters for the need for transparency and independent review of the clinical trial data. Pfizer has made fostering transparency with regard to clinical trial data part of its corporate policy, as have U.S. and European pharmaceutical trade organizations. (App000342 – App000343 ¶¶ 27-28.) The U.S. Institute of Medicine has made the same endorsement. (App000342 – App000343 ¶ 28) As has the FDA itself, when it acknowledged not only the need to disclose data relied upon for licensure, but that it be released straightaway. That is why FDA regulations provide that "[a]fter a license has been issued, the … 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).

With respect to the Pfizer vaccine in particular, as quoted *supra*, numerous politicians have called for greater transparency concerning the FDA's approval of the Pfizer vaccine. As noted, even the current President of the United States has repeatedly urged the government to "**make all of it [the vaccine data] available to other experts across the nation.**" (*See* App000338 ¶ 2 (emphasis added).) Nor has the President retreated from this rhetoric, imploring during a "Global COVID-19 Summit" in September 2021 that the nations of the world must "exercise transparency to build vital public trust in these lifesaving tools." (App000339 ¶ 6.)

Transparency is critical because "[i]ndependent review is essential to scientific integrity." (App000163 ¶ 25.) "Professionals working in the scientific and healthcare professions all seek second opinions." (App000009 ¶ 12.) Likewise, the "[c]ollective efforts of all scientists in the United States will produce more insights at a quicker pace than if the FDA hoards data, prohibiting others from getting involved." (App000011 ¶ 16.) With regard to the Pfizer vaccine, the need for peer review is even more acute because of the "drastically shorted regulatory approval process" that the FDA undertook to rush the Pfizer vaccine to licensure. (App000009 – App000010 ¶ 14.) "It is nearly impossible that the FDA could have done everything it typically does in its review of a vaccine in the short time period within which Pfizer's vaccine was reviewed and approved." (*Id.*)

For true independent analysis to occur, half-measures will not do. "Scientists and healthcare professionals need **all** of the documents submitted by Pfizer to conduct a proper analysis" since missing even a single dataset could throw off any analysis. (App000162 ¶ 21. *See also* App000008 ¶ 10.) This is because "[a]ll scientific analyses rely on **complete** sets of information[.]" (App000162 ¶ 21.) "Attempting to recreate analyses on efficacy or safety without all the relevant data – data already limited by the short time period of the [Pfizer vaccine] trials – would prove useless." (App000009 ¶ 11.) As such, even though the FDA proposes a rolling production, that will do nothing to expedite the independent review.

The urgent need for the FDA to release the data sought by PHMPT can be seen from the media's shocked reaction to the FDA's request in this case to take 55 years to respond to the FOIA Request. For example, Reuters published an article titled: "Wait what? FDA wants 55 years to process FOIA request over vaccine data," and other media outlets have expressed similar surprise and often outrage that it would take so long to release the Pfizer data. (App000339 ¶ 7.) Furthermore, the shock was not confined to domestic media.

Independent review of the data is precisely what PHMPT is seeking here. It filed the FOIA Request within days of the FDA approving the Pfizer vaccine. The organization's website states that it "takes no position on the data other than that it should be made publicly available to allow independent experts to conduct their own review and analyses." (App000003 ¶ 5.) To achieve this goal, the site states that "[a]ny data received will be made public on this website."

ii. The Value of Independent Review is Lost if Not Done Forthwith

Time is of the essence with regard to reviewing the data sought in the FOIA Request. (App000011 ¶ 16.) Governments, employers, and individuals are making decisions every day regarding the Pfizer vaccine. The longer it takes the FDA to produce documents responsive to the FOIA Request, the more of those decisions will be made without the benefit of any independent review of the Pfizer data. The best way to improve decision making and otherwise reassure Americans about the decisions being made is to have independent review of the Pfizer data. Thus, the value of the information decreases every day that the FDA delays in producing the full data set.

In many ways, what is occurring is unprecedented. "An estimated 9.5 billion doses [of the COVID-19 vaccines] have been administered thus far making it the largest medical intervention in the history of humankind." (App000107 ¶ 14.) Not only are the COVID-19 vaccines unparalleled in scale, the way in which that scale has been achieved is also unprecedented. There is no other consumer product that the federal government has ever mandated that millions of Americans receive in order to earn a living.

The unprecedented nature of these mandates have been met with skepticism and protests. According to a tracking poll by Morning Consult, as of mid-November 2021, 27% of the respondents in the United States were either uncertain or unwilling to be vaccinated. Of those respondents, 48% were skeptical about being vaccinated because they were either "worried the

clinical trials moved too fast" (29%), do not "think the vaccine will be effective" (9%), or do not "trust the companies making vaccines" (10%). Having multiple trusted independent authorities review the safety and effectiveness data sought in the FOIA Request, which is what PHMPT intends, will almost certainly play a role in how these people evaluate their vaccine decisions. (*See* App000342 ¶ 27 (Pfizer policy statement noting that transparency of clinical trial data "fosters trust"); App000342 – App000343 ¶ 28 ("In a time of increasing public scrutiny, transparency of regulatory decision making leading to the approval of … vaccines for COVID-19 is important to ensure patient and stakeholder trust.").)

Furthermore, skepticism regarding the Pfizer vaccine is not unfounded, nor is it confined to the general populous. Prominent members of the scientific community have raised serious concerns regarding its clinical trials, its safety and efficacy, and the FDA's drastically abbreviated licensing process. "There has never been a vaccine approved [by the FDA] in such a short time period." (App000009 – App000010 ¶ 14.) The abbreviated schedule led researchers to question everything from the adequacy of the data the FDA relied on to whether the FDA permitted Pfizer to use fewer test subjects than would normally be required. In an article published last month in the medical journal "BMJ Evidence-Based Medicine," its five authors noted that there "are issues in COVID-19 vaccine trials that merit scrutiny" and then went on to discuss some of those unresolved issues in detail. (App000342 – App000343 ¶ 28.) Other scientists have noted that adverse reactions in VAERS and other data signal tremendous issues with the safety of the Pfizer vaccine. (*See, e.g.*, App000162 – App000163 ¶ 23 ("The combined failure of COVID-19 vaccine protection to last even six months and the catastrophic number of serious adverse events reported have created an urgent need for the scientific community to study and the public to understand what has gone wrong in the United States and how we can remedy the public COVID-19 vaccine program

currently being administered by the CDC/FDA.").)

Further contributing to the unprecedented nature of the situation is that Americans, if injured, cannot sue Pfizer, the FDA, or the doctors that administer the vaccines. 42 U.S.C. § 247d-6d. There is almost no other product where an injured consumer cannot sue the company that makes, sells, and profits from the product. Thus, consumers, who in many cases are being mandated by the government to receive the COVID-19 vaccines, have no way to be compensated if they are injured nor do they have any way to force the manufacturer to improve the safety of the product.

This extraordinary state of affairs leads to an **unprecedented** need for transparency. *See Bloomberg, L.P.*, 500 F. Supp. 2d at 378 (holding that the need for the public to have information collected by the FDA disseminated widely and reviewed by independent experts was a major factor in the need for expedited production). Currently, the only entities that have reviewed the full data are Pfizer and the FDA, both of which are immune from suit and are under enormous political pressure to deliver vaccines quickly. If Americans cannot say no and cannot sue for harm, then the safety and efficacy of the vaccines must be put through the most rigorous review possible. In the scientific and healthcare fields, rigorous review means independent peer review.

Nevertheless, peer review will be meaningless if it cannot happen for another 55 years. Even if delayed one year from now, the value of the review will be lost because the pandemic and technology will have moved on. That is why rapid production of all the documents within 108 days, at most, even if unprecedented, is necessary. Governments, employers, and individuals are making decisions about the vaccines every day and the data can potentially shape how we move forward in continuing to combat an ongoing global pandemic.

iii. The FDA's Approval of the Pfizer Vaccine is Government Activity

The FOIA Request also meets the third factor required for a showing of urgent need because the information PHMPT seeks concerns actual federal government activity. It involves the sufficiency and accuracy of the review the FDA conducted to license the Pfizer vaccine, and more broadly, the central role HHS – FDA's parent department – played in developing, testing, and promoting Pfizer's vaccine. As such, there is no reasonable argument that PHMPT's FOIA Request seeks anything other than documents concerning "identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44 (c)(2)-(3).

II. THE FDA'S POSITION IS IRRATIONAL AND HIGHLY CONCERNING

The FDA claims it has identified over 329,000+ pages of documents, in addition to data, that are responsive to the FOIA Request. (Dkt. No. 20 p. 3.) Nevertheless, it proposes to produce just 500 pages every month for nearly 55 years before it will fully produce the documents. None of the FDA's arguments for this position in the parties Second Joint Report justifies its patently irrational proposal to produce documents over the course of the next five *decades*! And none of its arguments acknowledge the most obvious factor: the importance and unprecedented nature of the documents at issue. Each of the FDA's arguments are addressed in turn.

1. The FDA Has the Resources to Expeditiously Produce all Responsive Documents

The FDA's first argument for wanting to take decades to produce is that its FOIA office does not have the capacity to produce the documents any faster. This argument is specious on numerous levels. First, while the FOIA office itself may only have a few employees, the FDA has 18,062 employees as of 2020. (App000339 ¶ 5.) For expedited productions, courts regularly instruct agencies to redirect resources, or to acquire new resources, in order to expeditiously produce documents. *E.g., Diocesan Migrant & Refugee Services, Inc. v. United States Immigration and Customs Enf't*, No. EP-19-CV-00236-FM, 2021 WL 289548, at *4 (W.D. Tex.

Jan. 28, 2021) (nothing that by using software programs, and reassigning personnel to the task, ICE was able to review 86,000 potentially responsive documents within four months in order to meet the court's production deadline); *Open Soc'y. Justice Initiative v. Cent. Intelligence Agency*, 399 F. Supp. 3d 161, 169 (S.D.N.Y. 2019) (requiring the Department of Defense to produce documents at a rate of 5,000 pages a month, "even if meeting this demand calls upon DOD to augment, temporarily or permanently, its review resources, human and/or technological").

Furthermore, the FDA's claimed lack of resources rings hollow in the face of the fact that the public has paid enormous sums to develop, manufacture, and market the Pfizer vaccine, and the public is statutorily entitled to see what it is getting for its money. This includes giving Pfizer $1.95 billion of taxpayer money to promote development of its vaccine and then an additional $15.7 billion of taxpayer money to purchase this product. Beyond the money directly handed to Pfizer, federal health authorities spent $18.75 billion of taxpayer money promoting this product. Thus, federal health authorities have had no issue with rapidly spending in total at least $35 billion of American taxpayer money supporting Pfizer's vaccine. Even if one just takes the $17.6 billion given directly to Pfizer, that amounts to giving the company over $48 million in taxpayer money every day for over a year, plus spending more than that amount per day promoting Pfizer's product. Given this, these same federal health authorities cannot claim that they are incapable of meeting their statutory requirements to produce documents due to a lack of resources.

As noted, there is near universal agreement that transparency and independent review are extremely valuable for society. The FDA must therefore explain why it could not use a fraction of the billions of taxpayer dollars it has given to Pfizer for its vaccine in order to ensure a timely production of the documents the FDA used to approve the vaccine's licensure.

2. Even Absent the Current Exigency, Courts Regularly Order Agencies to Produce Large Volumes of Documents in Short Periods of Time

The FDA further tries to justify its incredulous request to produce just 500 page per month by arguing this rate has been adopted by other courts, even when the production would take years to complete. The FDA's claim is highly misleading.

First, the FDA cites sixteen cases in the November 11, 2021 Joint Report where it says the court directed the agency to produce documents at a rate of 500 per month. (Dkt. No. 20 pp. 4 n.3, 7-8.) However, in **none** of those cases did the Court or agency decide that the production qualified for expedited processing. *See, e.g., Freedom Watch v. Bureau of Land Mgmt.*, No. 16 Civ. 2320 (D.D.C.), Minute Order of June 13, 2017 (plaintiff failed to show any reasons for expediting). In other cases cited by the FDA, the requester never even questioned the rate of production or sought expedited production. *See, e.g., Judicial Watch, Inc. v. U.S. Dep't of State*, No. 15 Civ. 687 (D.D.C.), Minute Order of April 4, 2017; *Citizens United v. U.S. Dep't of State*, No. 15 Civ. 1720 (D.D.C.), Dkt. 11 ¶ 10. In other cases, the underlying acts that the FOIA request concerned occurred years or even decades before the requests were made, meaning that there was no urgency to the requests. *See, e.g., Colbert v. FBI*, No. 16 Civ. 1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (seeking documents concerning the D.B. Cooper incident in 1971).

Likewise, in none of those cases did the Court contemplate a production schedule that would last over five decades. To the contrary, most courts reviewing expedited productions seek to ensure productions are completed expeditiously. *See, e.g., Diocesan Migrant & Refugee Services, Inc.*, 2021 WL 289548, at *4 (setting a goal for the agency to produce documents within four months); *Inst. for Justice v. Internal Revenue Serv.*, 1:18-CV-01477 (CJN), 2021 WL 4935536, at *7 (D.D.C. July 8, 2021) ("it would be inappropriate for productions to extend over multiple years"); *Seavey v. Dept. of Justice*, 266 F. Supp. 3d 241, 248 (D.D.C. 2017) (rejecting

FBI proposal to produce 500 pages per month over the course of 17 years).

Instead, where expedited processing is warranted and an agency refuses to timely produce, courts regularly require production at many times the FDA's proposed 500 pages per month. The following are samples of production rates endorsed by such courts before and during the pandemic:

- In *Diocesan Migrant*, 2021 WL 289548, to meet the court's deadline, ICE produced 86,000 pages in four months, for an average rate of **21,500 pages per month**.
- In *Treatment Action Group v. FDA*, Case No. 15-cv-00976-VAB (D. Conn. 2016) the FDA produced 82,668 pages and 1,045 electronic files in approximately 7 months for an average production rate of approximately **11,800 pages per month**.
- In *Seife v. FDA*, 492 F. Supp. 3d 269, 273 (S.D.N.Y. 2020), the FDA agreed to produce 45,000 pages in approximately four months for an average of **10,000 pages per month**.
- In *Open Soc'y Justice Initiative v. CIA*, 399 F. Supp. 3d 161 (S.D.N.Y. 2019), the CIA produced 288,000 pages at the rate of around **8,000 pages per month**.
- *In NRDC v. Dep't of Energy*, 191 F. Supp. 2d 41, 43 n.5 (D.D.C. 2002) the court ordered the Department of Energy to produce around **7,500 pages in a month**.

Even with these large production numbers, none of these cases involved documents as consequential to American life as the documents PHMPT seeks here. The *Seife v. FDA* matter presents an apt example. There the plaintiff sought "documents and records regarding the testing and approval process for eteplirsen … a drug … for the treatment of Duchenne Muscular Dystrophy …, a rare neuromuscular disease." 492 F. Supp. 3d at 271, 273. In 2016 the FDA granted "accelerated approval" of eteplirsen. *Id.* at 272. Nevertheless, the next year the FDA produced tens of thousands of pages of documents concerning eteplirsen, most of which were substantially similar to those at issue in this case, many requiring redactions. *Id.* at 273. *Seife*

concerned a product rarely used by a small fraction of the population, but the FDA was able to timely produce all the responsive documents. *Id.* at 271. This fact raises serious questions here about why, where PHMPT seeks similar documents concerning a liability-free vaccine mandated by the government for use by millions of Americans, the FDA has proposed a monthly production rate **20 times slower** than it produced in *Seife*. Similarly, *Treatment Action Group* concerned the approval of two Hepatitis C drugs, again drugs that are not mandated nor used by nearly the same number of people who will receive the Pfizer vaccine, but still the FDA could produce documents similar to those sought in the instant case at an average rate of nearly 12,000 pages per month, at one point even producing 25,000 pages, with redactions, in just six weeks. Case No. 15-cv-00976-VAB (D. Conn. 2016) Dkt. No. 87 pp. 4-5.

In addition, the FDA has simply proposed producing 500 pages per month regardless of whether those pages contain exempt material or are otherwise easily producible. "The D.C. Circuit has found that unreasonable delays in disclosing non-exempt documents violate the intent and purpose of the FOIA, and the courts have a duty to prevent [such] abuses." *Clemente v. Fed. Bur. of Investigation*, 71 F. Supp. 3d 262, 269 (DDC 2014) (internal quotations omitted). Given this goal, the FDA's one size fits all approach is inappropriate, and a higher rate of production for at least some of the documents is achievable and necessary.

The FDA also tries to argue that its proposed 55+-year production schedule is PHMPT's fault for requesting too many documents. This is a red herring. PHMPT merely requested the documents that are supposed to be publicly available under 21 C.F.R. § 601.51(e), and as explained above, all of those documents are required for a true independent evaluation of the data.

3. The FDA is Dramatically Overemphasizing the Risk of Inadvertent Disclosure

The FDA also claims that an expedited production of documents could risk the inadvertent disclosure of personal privacy information. This concern, however, is unfounded and greatly

overblown because the FDA's own regulations require that "[t]he names and other information which would identify patients or research subjects should be deleted from any record **before it is submitted to the Food and Drug Administration**." 21 C.F.R § 20.63(b) (emphasis added). Thus, the documents submitted by Pfizer, which are the subject of the FOIA Request, would have already been anonymized, and therefore, the risk of disclosing such information is minimal.

4. The FDA's Regulations Require Immediate Production

The FDA further argues that even though 21 C.F.R. § 601.51(e) states that the agency must make "the biological product file … **immediately available for public disclosure**" that has no bearing on its over 55-year production schedule. This claim makes a mockery of the regulation. It is hard to see how anyone could interpret "immediately available" as being intended to mean that the documents would be made available to the public over 55 years after the vaccine was licensed. The FDA further asserts that the regulation does not actually require production of anything to the public and, instead, requires that the public make a separate FOIA request in order for those documents to actually become public. A wholistic reading of the regulation reflects the opposite. In the paragraph preceding paragraph (e), the regulation instructs that the "FDA will make available to the public *upon request*" other documents concerning pre-licensure applications, and specifically states that "[p]ersons wishing to request this information shall submit a request under" FOIA. 21 C.F.R. § 601.51 (d)(2) (emphasis added). In contrast, paragraph (e) says nothing about a member of the public needing to make a specific request in order to view the information listed in that paragraph regarding vaccine licensure applications. This difference in language should reflect that paragraph (e) obligates the FDA to make those documents (*i.e.*, the documents sought in the FOIA Request) "immediately available" just as it says.

CONCLUSION

For the foregoing reasons, during the upcoming scheduling conference, the Court should

order the FDA to produce all documents responsive to the PHMPT's FOIA Request on or before March 3, 2022, which is 108 days from the parties Second Joint Report to the Court.

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SIRI & GLIMSTAD LLP

Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
Gabrielle G. Palmer, CO Bar No. 48948
200 Park Avenue
New York, New York 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
gpalmer@sirillp.com

HOWIE LAW, PC
John Howie
Texas Bar Number: 24027239
2608 Hibernia Street
Dallas, Texas 75204
Tel: (214) 622-6340
jhowie@howielaw.net

Attorneys for Plaintiff