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

OPPOSITION TO FDA'S REQUEST FOR AT LEAST 75 YEARS TO RELEASE PFIZER'S BLA DOCUMENTS

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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 opposition to the FDA's request for at least 75 years to release 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

Defendant, incredibly, focuses its opening brief on the idea that fairness requires it to take decades to produce the Pfizer vaccine licensure documents. Fairness? Fairness would be giving millions of Americans who are mandated to receive this liability-free vaccine today assurance regarding the FDA's review by allowing independent scientists access to the same data the FDA reviewed, without making them wait decades. Fairness would be allowing Americans injured by the vaccine today, who cannot sue Pfizer or anyone else for the harm, hope that independent scientists with access to that data can more readily develop treatments for their ailments. Fairness would be our federal health authorities allocating more than one person spending a few hours each month to review Pfizer's documents for public disclosure after having given Pfizer over $17 billion of taxpayer money to develop and market the product. Fairness would be releasing the documents so that independent scientists can have this data to assist in addressing serious issues of waning immunity, diminished efficacy, vaccine-immunity evading variants, etc. Fairness would be producing documents that the American taxpayers paid for while those same people are still alive, not decades after most are dead. That would be fairness to the American people.

All of the FDA's griping about fairness comes down to one thing, and one thing alone: it has not sufficiently staffed its FOIA office to properly meet its legal obligations to respond to the requests it receives. In passing FOIA, Congress made the policy decision that it wanted to ensure

transparency, and it knew that transparency delayed is transparency denied, therefore it required agencies like the FDA to produce documents as soon as practicable where the request qualifies for expedited processing. That is the FDA's legal obligation: to promptly produce records. The FDA is not permitted to thwart Congress' policy choice by understaffing its FOIA response office. Numerous cases show how other agencies, when dealing with a production that is eligible for expedited processing, have transferred staff, or hired more staff, in order to promptly comply with its statutory obligations. Here, for the reasons explained in PHMPT's opening brief, the instant FOIA request is the prime example of one that requires expedited processing, and as a result, the FDA cannot be heard to claim that it has too few people to meet its statutory obligations.

Law journal articles, ABA publications, and legal decisions all reflect a document review rate of at least 50 pages per hour per reviewer, and often far more, for reviewing documents for production in litigation – where those reviewers are also searching the documents for relevance, responsiveness, privilege, hot documents, confidentiality designations, attorney-eyes only designation, trade secrets, certain personal information, coding by category, etc. Those are tasks far more complex than called for here. For the simpler task of reviewing for only personally identifiable information and trade secrets under FOIA, assuming a low average of 50 pages per hour per person, even to review the hundreds of thousands of pages the FDA estimates, the agency would need just 19 reviewers to work full time for 12 weeks to review and produce these documents – which is a tiny fraction of its approximately 18,000 employees or, if it outsources the review as is common in litigation reviews, a mere rounding error in its approximately $6.5 billion budget and an even smaller rounding error of the over $17 billion given by the federal government to Pfizer. Plaintiff, in fact, obtained a quote from the e-discovery company BIA dated December 10, 2021 to conduct this precise review of 400,000 pages. BIA concluded that the review could

be completed in a period of 6-8 weeks with 10 reviewers and 1 team leader for a total price tag of approximately $132,000. (App000634 ¶ 5.) **The FDA should be directed to do precisely that.** It should do what everyone else in this country must do – **follow the requirements of federal law**.

Companies do not get to delay paying taxes because they don't have enough tax personnel. They don't get to avoid complying with environmental regulations because they don't have enough compliance officers. They don't get to avoid responding to a U.S. Attorney's subpoena because they don't have enough staff to review the documents. They must follow the law, and so must federal agencies. And here the law says "promptly" and "as soon as practicable," and the regulation says, "immediately available." All of this statutory and regulatory language is intended to ensure transparency. These requirements are utterly defeated if the documents are not produced forthwith. Waiting for transparency until almost everyone alive today is dead makes a mockery of FOIA and of the promise of transparency.

Showing just how misguided the FDA is in its approach, in its brief and declaration in support of same, the FDA ignores all the arguments made by Plaintiff with regard to fairness in the parties' First Joint Report and Second Joint Report. (Dkt 18 ¶ 15; Dkt 20 ¶¶ 2-3.) It ignores the incredible unfairness to the American people to not have access to the Pfizer documents.

Instead, the FDA repeatedly discusses in its motion papers what is fair to the vaccine sponsor, meaning Pfizer, and "the interests of the vaccine sponsor." (Dkt 18 ¶ 15; Dkt 20 ¶ 2.) Putting aside that this is not a real concern in this case, if Pfizer is concerned about its trade secrets, then it has more than sufficient resources to perform the necessary review and inform the FDA what it believes should be withheld from disclosure in a timely manner. This is not a novel concept as other FOIA matters have been resolved in this manner wherein the FDA has adopted redactions proposed by the creator of the documents based on the company's representations that the

documents covered confidential commercial information that would cause harm if disclosed. In fact, if Pfizer spent just .01% of the $17 billion in taxpayer money it received from the federal government for its liability-free mandated product, it could complete this review in less than a week. At a minimum, Pfizer's interests must be viewed through the lens of its obligation to the American people who are underwriting its profits for a product the government has marketed for Pfizer, given immunity from harm, and mandated American take under penalty of exclusion from civil society.

The FDA also says it is unfair to other pending FOIA requesters to prioritize this request. First, since this request qualifies for expedited processing, it must by statute take priority over all other requestors. Second, any unfairness to other requestors is outweighed by the interest of millions of Americans who are being affected by the Pfizer vaccine in having independent scientists review the Pfizer data. Third, any unfairness falls squarely on the shoulders of the FDA for *choosing*, even now during a pandemic, to only have 10 people in its FOIA office (only 8 of whom with experience) despite a budget of over $6.5 billion and over 18,000 employees. Regardless of whether the FDA has made FOIA or transparency a priority, it is an obligation imposed by law and one that must be upheld by the courts despite any claimed hardship it may impose. For the hardship suffered by the American people in the alternative far outweighs any felt by the agency.

ARGUMENT

I. THE FDA ASKS THE COURT TO GIVE IT OVER 75 YEARS TO PROCESS THE FULL REQUEST

The FDA initially disclosed that responding to the instant FOIA request would involve producing 329,000+ pages. As stated in PHMPT's opening brief, at the FDA's proposed 500 pages per month, it would take 54 years and 10 months to process the instant request. The FDA

has since clarified its estimated pages and, with its revised figures, the FDA's current production schedule will require at least 75 years to complete.

The FDA has clarified that, in addition to the previously estimate, the response includes another "approximately 39,000 pages" of BLA "supplements, amendments, and product correspondence" (App000633 ¶ 3), plus "tens of thousands of additional pages" of "records that may be supportive of the BLA" (*Id.*), plus at least 126 data files from Pfizer, many of which the FDA says have over ten thousand rows. (Dkt. No. 22 p. 3.) The FDA states it would like to treat twenty rows in each data file as one page for its monthly production quota. (Dkt. No. 22 p. 9 n.6.) The page counts increased because the agency initially inappropriately limited the scope of Plaintiff's request without any agreement from Plaintiff. Now they have chosen to provide a more accurate page count based on the initial, plainly worded request seeking all documents enumerated in 21 C.F.R. § 601.51(e). However, the FDA has so far refused to provide a more precise count of the "tens of thousands of additional pages" or the total rows in all spreadsheets. (App000633 ¶¶ 3-4.) Instead, the agency argues that Plaintiff's request is overly broad – despite it asking for precisely what is enumerated in 21 C.F.R. § 601.51(e), nothing more. In fact, Plaintiff excluded from the documents any of those already made public via the Vaccine Adverse Event Reporting System. The scope of Plaintiff's request is clear and has been consistent; any misinterpretation or one-sided narrowing of same is on the FDA's part.

The FDA's 20 lines per page estimate is ridiculous in terms of estimating how long it will take to review a spreadsheet. The reason why data is put in a spreadsheet is so that different types of data can be easily identified and separated by columns. If there is either personally identifiable or trade secret information in a column which needs redaction, which as explained below is unlikely, then the FDA can identify same and, as already proposed by Plaintiff, the parties can

discuss redacting the entire column. In that case, a line-by-line review is unnecessary or at the very least can be performed very quickly.

Putting aside that 20 rows per page is an inflated estimate of the time to review, at an average of 12,000 rows per data file, at the FDA's proposed 20 rows per page, the 126 data files adds around 75,000 additional pages. (Dkt. No. 22 pp. 3, 9 n.6.) And assuming the FDA's amorphous "tens of thousands of additional pages" amounts to 20,000 additional pages, then the grand total appears to be at least 451,000 pages. This is the best estimate Plaintiff has at this time.

Even assuming the FDA produces the 12,000 pages it claims it will produce by the end of January, that still leaves at least 439,000 pages to be produced. This number pales in comparison to the millions of pages regularly produced in commercial litigations. Nevertheless, at the rate of 500 pages per month proposed by the FDA, the agency is asking that this Court give it at least **75 years** to produce all the documents. The average life expectancy in the United States in 2020 was 77.8 years. (App000634 ¶ 6.) Thus, the FDA is asking this Court to wait until almost everyone alive today is dead to produce documents that are supposed to be "immediately released" after approval.

II. FEDERAL LAW REQUIRES THE FDA TO "IMMEDIATELY RELEASE" THE REQUESTED DOCUMENTS

Federal regulation requires that upon licensure of a vaccine, the agency is to make "the biological product file … immediately available for public disclosure." 21 C.F.R. § 601.51(e). The FDA obviously adopted this regulation when it still believed in transparency, accountability, and open government. That it has retreated from these positions does not mean it can ignore the same federal laws every American must follow.

The FDA previously argued that this regulation creates no right for the public to obtain these documents, rather it merely allows the agency to produce what are otherwise private

documents. However, that argument is belied by the language of the regulation itself. The request here seeks the information listed in 21 C.F.R. § 601.51(e). Directly above section (e) is another section that concerns obtaining documents. That section, section (d), provides that the "FDA will make available to the public upon request" other documents concerning pre-licensure applications, and that "[p]ersons wishing to request this information shall submit a request under the Freedom of Information Act [FOIA]." 21 C.F.R. § 601.51 (d)(2). In stark contrast, paragraph (e) says nothing about a member of the public needing to make a FOIA request. Rather, it enumerates that the information that must be made "immediately available" to the public upon licensure. This difference reflects that paragraph (e) obligates the FDA, separate and apart from FOIA, to make those documents (i.e., the documents sought in the current request) "immediately available" just as it says.

This is also plain from the fact that paragraph (e) also sets its own standard as to what information should be redacted. For example, (e)(2) provides that the FDA is to make the study's "protocol" immediately public unless it contains "trade secrets and confidential commercial or financial information." Similarly, (e)(3) provides that "[a]dverse reaction reports" and "product experience reports" are to be made immediately available "after deletion of … names and any information that would identify the person using the product." If section (e) was not intending to create a right separate and apart from FOIA, there is no need for these redundant redaction obligations. Hence, this again further makes plain that the disclosure obligation under 21 C.F.R. § 601.51(e) is separate and apart from FOIA.

The Court should, therefore, respectfully require the FDA to abide by its own regulations, just as all Americans must abide by the FDA's regulations, and "immediately disclose" all the information required to be immediately disclosed under 21 C.F.R. § 601.51(e).

III. FOIA DEMANDS THE FDA TIMELY PRODUCE THE DOCUMENTS

The FDA also has a separate duty to disclose the documents requested under FOIA.

A. FOIA REQUIRES PRODUCTIONS TO BE MADE "PROMPTLY" AND EXPEDITED REQUESTS SUCH AS THE ONE AT ISSUE HERE MUST BE COMPLETED "AS SOON AS PRACTICABLE"

The FDA explains how it must take incredible care to abide by the statutory requirements to redact any information required by FOIA. That it must safeguard Pfizer's trade secrets by conducting a line-by-line, word-by-word review which will take decades because no shortcuts can be taken. That it must exactingly abide by the FOIA's redaction requirements. Taking the FDA at its word that the FOIA obligations must be strictly followed, the FDA must also give as much or more gravity to the primary requirement under FOIA – that it "shall make the records **promptly** available to any person" and that, when as here, a request qualifies for expedited processing, it is to be produced at even greater haste "**as soon as practicable**." 5 U.S.C. § 552(a)(3), 5 U.S.C. § 552 (a)(6)(E)(iii) (emphasis added). Congress made plain in FOIA that when there is an "urgency to inform the public concerning actual or alleged Federal Government activity," expedited processing beyond the routine "promptly" requirement is demanded. There frankly could not be an instance that more squarely falls into the criteria for expedited processing. At issue is a product for which the government has granted immunity to liability, has mandated millions of Americans to receive, has given Pfizer millions of dollars for, and was approved within 108 days. What Plaintiff seeks is to review the documents the government relied upon in its action of licensing this product for the public's use. There is, therefore, a dire urgency for the public to have full transparency and review of the FDA's quintessential government activity of licensing Pfizer's COVID-19 vaccine. *Id.* But still, where this need for expedited processing is crystal clear, the FDA shockingly appears to argue that this threshold is not met.

Incredibly, the FDA justifies asking for decades to produce documents by noting that FOIA does not have "a specific timeframe for the release of records." (Dkt. No. 22 p. 2.) Putting aside the elementary school understanding of the word "promptly" and "as soon as practicable," and the purpose of FOIA, courts have made clear that, "Congress recognized that delay in complying with FOIA requests is 'tantamount to denial.'" *Elec. Privacy Info. Ctr. v. Dept. of Justice*, 416 F. Supp. 2d 30, 40 (D.D.C. 2006) (quoting H.R. Rep. No. 93–876, at 6 (1974), 1974 U.S. Code Cong. & Admin. News, pp. 6267, 6271). Likewise, the D.C. Circuit, the circuit with the most experience concerning FOIA, has "acknowledged that 'stale information is of little value.'" *Id.* (quoting *Payne Enterprises, Inc. v United States*, 837 F.2d 486, 494 (D.C. Cir. 1988)). That is why "[t]he 1996 amendments to FOIA creating the statutory right to expedition in certain cases 'underlined Congress' recognition of the value in hastening release of certain information.'" *Id.* (quoting *Edmonds v F.B.I.*, 417 F.3d 1319, 1324 (D.C. Cir. 2005)).

As shown in PHMPT's complaint and in its opening brief, its instant FOIA request is exactly the type of request that Congress had in mind for expedited processing under the FOIA statue. 5 U.S.C. § 552 (a)(6)(E)(v); 21 C.F.R. § 20.44 (c)(2)-(3). PHMPT is unquestionably an organization engaged in the dissemination of information. (Dkt. No. 1 ¶ 4; Dkt. No. 26 p. 14.) The FDA has not challenged this fact. All the documents sought in the FOIA request are urgently needed to allow independent scientists to review the FDA's work and to provide assurance to the public that the liability-free vaccine they are being mandated to receive has truly passed the most rigorous review possible. (Dkt. No. 16 pp. 14-16.) Politicians, academics, and the scientific community all agree on this point. (*Id.*) Additionally, not only are the documents sought central to the largest media story of our time – the fight against COVID-19 and the vaccines deployed in that fight – but as shown, the FDA's claim that it would require decades to produce documents has

itself generated substantial media attention. (Dkt. No. 26 p. 16); *see also Brennan Ctr. for Justice at NYU School of Law v Dept. of Commerce,* 498 F. Supp. 3d 87, 97 (D.D.C. 2020) (requiring expedited processing of a FOIA request because the 2020 Census had generated substantial media attention and there was a need to establish the integrity of the Census). Furthermore, the need for this information will be lost if all the documents are not promptly produced because people and governments are making decisions regarding the Pfizer vaccine now, not in 75 years. (Dkt. No. 26 pp. 17-19.)

An agency like the FDA cannot satisfy Congress' expedited processing requirements solely by giving the FOIA request prompt administrative attention, or by giving priority to only the first 12,000 pages that PHMPT was seeking by November 17 in order to conduct a quick initial assessment. *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41 (holding that, where a request is entitled to expedited processing, the agency must produce documents in a timely manner). "What matters … is … when the documents are actually released." *Id.* Notably, the FDA's brief is misleading as to the course of communications between the parties. It makes it appear as if Plaintiff agreed to some initial list of documents to the exclusion of others when, in reality, the list provided, with a request the FDA produce by November 17, 2021, was merely intended to get an initial sense of what was in the product file so that Plaintiff could create a priority list for the entire production to occur over a 30-day period and, later, its compromise position of no more than 108 days. The FDA knows that this information is useless in conducting an independent review and was merely intended to get an overview, yet treats it as if it's providing something valuable by the end of January when in reality is well aware that all this has done is create a two-month delay without adding value to the public. *See* full exchange between counsel included at App000633 ¶ 2. As such, the FDA cannot possibly claim that releasing a small subset of the documents when pressed

or the universe of responsive documents over the course of 75 years meets its statutory obligation to "process" the FOIA request "as soon as practicable." 5 U.S.C. § 552 (a)(6)(E)(iii).

Absent from the FDA's arguments is any acknowledgement of the declarant scientists and researchers' explanations that until the entire universe of documents is produced, Plaintiff will not be able to conduct a proper review to evaluate the government's licensure of the product at issue. "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." (Dkt. No. 26 p. 16.) Instead of acknowledging this issue, the FDA repeatedly demands that Plaintiff narrow its request to target only a subset or subsets of the entire biologic product file, ignoring the fact that all of the data is necessary in order to conduct an adequate analysis.

Nor can the FDA claim that it must take decades to process PHMPT's request because it received 329 other pending FOIA requests before PHMPT's request. (Dkt. No. 22 p. 11.) This is a specious claim given that, "[p]rocessing expedited FOIA cases takes precedence over processing other non-expedited FOIA cases." *Brennan Ctr. for Justice at New York Univ. School of Law v. United States Dept. of State*, 300 F. Supp. 3d 540, 549 (S.D.N.Y. 2018); *Brennan Ctr.*, 498 F. Supp. 3d at 100-01 (stating that because the request qualified for expedited processing the agency needed to move the request to the front of the line of requests to be processed); *Edmonds v F.B.I.*, No. 02-1294 (ESH), 2002 WL 32539613, at *2 (D.D.C. Dec. 3, 2002) (same). Simply put, the "hardship on other FOIA requesters is not a bar to relief" where the Court finds that expedited processing is warranted because the "substantial interests" of PHMPT in obtaining the requested documents regarding the Pfizer vaccine "outweigh the hardship to Defendant[] and other requesters." *Brennan Ctr.*, 498 F Supp 3d at 103 (internal quotations omitted); *see also Ctr. for*

Pub. Integrity, 411 F. Supp. 3d at 14 (noting that FOIA requests often overlap and that processing of documents for one FOIA requests will assist in responding to other similar requests).

Moreover, the FDA's obligations do not stop at simply putting PHMPT at the head of the line. *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41. Expedited processing means that the agency is required to actually produce the documents as soon as practicable. *Id.* "Unless the requests are processed [i.e., the documents are produced] without delay, [PHMPT's] right to expedition will be lost." *Id.*; *see also Brennan Ctr.*, 498 F. Supp. 3d at 103 (finding that where the requestor had proven it was entitled to expedited processing, it was "entitled to expedited processing by a date certain"); *Open Socy. Justice Initiative v Cent. Intelligence Agency*, 399 F. Supp. 3d 161, 167 (S.D.N.Y. 2019) (focusing on the actual date of production after noting that meeting the date would put the request in priority over other requests).

Respectfully, "[t]he Court cannot 'simply ... take at face value an agency's determination that more time is necessary.'" *Brennan Ctr.*, 498 F. Supp. 3d at 100 (quoting *Elec. Privacy Info. Ctr. v Dept. of Justice*, 416 F. Supp. 2d at 37). The obligations under FOIA must be honored and hence, the FDA should review for information that needs redaction, but it must at the same time conduct that review in a manner that results in the documents being produced "as soon as practicable." *Brennan Ctr.*, 498 F. Supp. 3d at 103 (finding that, even though "inadvertent release of exempted documents" was a concern, that concern was not so great as to warrant dramatically slower production); *Diocesan Migrant & Refugee Services, Inc. v United States Immigration and Customs Enf't*, EP-19-CV-00236-FM, 2021 WL 289548, at *4 (W.D. Tex. Jan. 28, 2021) (noting that ICE had diverted resources and re-assigned 30% of its FOIA staff to first line review, and then 10-15 attorneys to spend half of every work day doing second line review in order to meet the court's expedited deadlines).

PHMPT is also willing to crowdsource sufficient funds for the FDA to hire contract attorneys to review the documents and produce them in less than 30 days. If the FDA would accept that help, it can produce these funds forthwith. However, the agency has declined this offer stating that "non-federal personnel…cannot perform federal work." (App000633 ¶ 4.) This claim rings hollow. When the FDA reviewed Pfizer's application to license its vaccine, the agency received at least $2,875,842 directly from Pfizer to expedite the licensing review. (App000634 ¶ 7.) As such, it is clear that the FDA's unprecedented quick approval time for Pfizer's vaccine was in many ways directly underwritten by Pfizer. (App000634 ¶ 8.) If the agency will now refuse to accept funds from Plaintiff to produce to the American people expeditiously the same documents it reviewed, then that decision makes crystal clear whose interests it really is serving.

It is embarrassing that our federal health agency gave Pfizer billions of taxpayer dollars, mandated Americans take its product, eliminated their ability to sue Pfizer for harms from this product, and then cries it is unfair to Pfizer if they have to produce these documents without a word-by-word review. Truly shameful. The pandemic is spiraling out of control and basic freedoms are receding in all directions. The solution is not for Plaintiff and the American people to wait until most people alive today are dead for the documents to be produced. Rather it is for the FDA to assign a few dozen of its 18,000+ employees *or* use a tiny rounding error fraction of its over $6.5 billion budget to hire professional document reviewers to get this done in less than 30 days, or at most Plaintiff's compromise position of no more than 108 days. Or it can allocate just .01% of the $17 billion the federal executive has given Pfizer which would be sufficient to hire enough contract attorneys to review and produce these documents in less than a week. *See Open Socy. Justice Initiative*, 399 F. Supp. 3d at 169 (directing expedited production "even if

meeting this demand calls upon DOD to augment, temporarily or permanently, its review resources, human and/or technological").

Plaintiff's request for production within 108 days is justified. If the FDA was able to review the universe of documents thoroughly enough to confirm and analyze Pfizer's data and conclusions, then certainly the agency can review the same universe looking only for the rare occurrence of trade secrets or personally identifying information. The FDA claims that Pfizer "submitted data to FDA on a rolling basis, even in advance of the formal BLA submission, meaning the substantive data review occurred over a longer period than the 108 days." (Dkt. No. 23 ¶ 35.) But Pfizer in a press release dated May 7, 2021, titled "Pfizer and BioNTech initiated the BLA by submitting the nonclinical and clinical data needed to support licensure…" of its COVID-19 vaccine announced that the "[d]ata to support the BLA **will be** submitted by the companies to the FDA on a rolling basis over the coming weeks, with a request for Priority Review." (App000634 ¶ 9) (emphasis added). Meaning, Pfizer began its rolling submission on May 7, 2021 and the vaccine was licensed on August 23, 2021, a total of 108 days from initial submission to licensure.

The only reason that the documents cannot be produced promptly is that the FDA has chosen to not properly allocate the resources to perform the required work. The FDA has repeatedly stated that the licensure of a COVID-19 vaccine and addressing the pandemic via same is its highest priority. This same branch of government reflected this priority by allocating enough resources to prioritize development, production, authorization, distribution, promotion, and licensing of the vaccine. It should now allocate adequate resources to transparency related to this vaccine. Releasing these documents is directly in line with this priority. It should act accordingly.

Corporations with a small fraction of the FDA's employees and resources must comply with all forms of statutory obligations. A company cannot claim that it only has 10 people in its accounting and tax departments and hence needs another 75 years to review its records in order to pay its taxes. But when it comes to the FDA's statutory obligation, the agency proposes to devote the equivalent of one person reviewing a few hours a month (even at its thumb-twiddling 8-minute-per-page rate) for the next 75+ years to fulfill its statutory obligation to produce these urgent records "as soon as practicable." It is a truly absurd position.

Putting this into perspective, private law firms manage to review and produce hundreds of thousands of pages per month in litigation when reviewing for far more than just the disclosure exemptions listed in FOIA, but also for relevance, responsiveness, privilege, hot documents, trade secrets, confidentiality designation, attorney-eyes only designation, coding by category, coding by request number, coding for second level reviews, certain personal information, etc. Law journal articles, ABA publications, and caselaw all reflect that at least 50 pages per hour, and often far more pages per hour, can be manually reviewed for this far more complex and involved review than the one required by FOIA, which here the Defendant submits only requires reviewing for trade secrets and personally identifiable information. (App000634 ¶ 10 – App000635 ¶ 13.) At this rate, it would take one reviewer just 10 hours to view the 500 pages that the FDA wants to produce in a month. Even at the FDA's ridiculous rate of 8 minutes per page, it would only take one reviewer 66 hours per month to review 500 pages. FDA also does not acknowledge the growing availability of artificial intelligence capable of almost completely automating privilege review. (App000635 ¶ 14.)

At bottom, the FDA does not treat its transparency obligations under FOIA to produce "as soon as practicable" as an actual statutory requirement. It instead just pays lip service to the

concept by saying that the "FDA is committed to transparency" but then does nothing to ensure that transparency. (Dkt. No. 18 ¶ 15.) "[M]erely paying lip service to [PHMPT's] statutory right does not negate the harm that results from the agency's failure to **actually** expedite its processing." *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 41 (internal quotations omitted, emphasis in original). In the end, whether the FDA values or is "committed" to transparency is irrelevant, Congress gave it a statutory obligation to produce expedited productions "as soon as practicable" and the Court must hold the agency to abide by that obligation – just as every other American must abide by federal statutes. *Payne Enterprises, Inc. v United States*, 837 F.2d 486, 494 (D.C. Cir. 1988) ("'unreasonable delays in disclosing non-exempt documents violate the intent and purpose of the FOIA, and the courts have a duty to prevent these abuses.'" (quoting *Long v U.S. I.R.S.*, 693 F.2d 907, 910 (9th Cir 1982))); *Clemente v Fed. Bur. of Investigation*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014) (quoting *Payne* and concluding that a "court therefore may use its equitable powers to require the agency to process documents according to a court-imposed timeline").

For these reasons, any partial adoption of the FDA's current production proposal will not result in a prompt or immediate result for the American public and so should be rejected by this Court. That will instead result in a piecemeal, foot-dragging schedule for which the parties will undoubtedly need repeated Court intervention to settle.

B. CLAIMED NEED FOR REDACTIONS IS OVERBLOWN

It is also simply untrue that the review the FDA argues it must conduct is as arduous as it claims. The FDA claims it must review for two categories of information: personal information that constitutes "a clearly unwarranted invasion of privacy" and trade secrets. (Dkt. No. 22 at 2.) As for personally identifiable information, this information has already been redacted by Pfizer before submission because that is what is required by the FDA regulations. 21 C.F.R § 20.63(b). ("The 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."). This likely explains why, when the FDA reviewed the two data files it produced to Plaintiff, the FDA found "that there was no exempt material in the data files" and hence "made no deletion or reductions in those files." (Dkt. No. 22 at 6.)

As for trade secrets, the FDA's regulations state that Pfizer was to designate trade secrets within its documents before submitting its documents or seek redactions in a "reasonable time thereafter." 21 C.F.R § 20.63(b). ("A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter. The designation must be in writing. … Any such designation will expire 10 years after the records were submitted to the Government.") In any event, most of the information submitted by Pfizer was clinical trial information – not trade secrets. It is deidentified patient level data.

As an example of how arbitrary and capricious the FDA acts regarding trade secret redactions, the FDA placed on its website its clinical trial review it conducted for the Pfizer vaccine which included an ingredient list for this product. One of the ingredients was redacted. Our firm submitted a FOIA request on behalf of a client to have that redaction lifted. (App000635 ¶ 15.) When it was finally lifted, it turned out that the redacted ingredient was "water for injection" (App000635 ¶ 16.) Literally "water."

The Court should respectfully not let the FDA play this same type of game here – pretending it must carefully review word-by-word to redact information and then finding something to redact to justify its review, when in reality almost everything submitted by Pfizer, without any review needed, will plainly not include trade secrets (*e.g.*, the hundreds of thousands

of pages of patient level data). In any event, Pfizer has already had an opportunity to designate any information it feels rises to the level of proprietary information.

If Pfizer has not already done so, the FDA can put the responsibility of designating information exempt from disclosure on Pfizer. Pfizer knows these documents and data inside and out. Pfizer has the responsibility to protect clinical trial participants' personally identifying information. Pfizer holds the interest in protecting trade secret information. Pfizer undoubtedly has the resources – as it expects to make $36 billion in sales on its COVID-19 vaccine this year alone (App000635 ¶ 17) – and the ability to promptly designate information it believes is exempt from disclosure and so, if the FDA cannot do so in an adequate period of time, the agency should notify Pfizer that it plans to produce the documents in full and lay the burden at Pfizer's feet to object to same.

C. THE FDA FAILED TO COMPLY WITH FOIA'S "DUE DILIGENCE" REQUIREMENT

An agency must show due diligence in responding to the request, even in situations where it is able to show exceptional circumstances exist for not being able to otherwise comply with statutory time frames. *See* 5 U.S.C. § 552(a)(6)(C). Here, the FDA has failed to show due diligence. Despite more than three months elapsing since Plaintiff's FOIA request was made, more than two months of communication through the parties' counsel, and the agency's own regulation which calls for these records to be made "immediately available" to the public, the agency has failed to do, *inter alia*, the following:

1. Provide a full index of the biological product file requested;
2. Provide a full index of the biologic license application within that file;
3. Provide approximate page counts/line counts for each portion of the biological product file;
4. Identify any documents or categories of documents which do not or are not expected to contain any exempt information;
5. Produce any documents that do not contain any exempt information;

6. Identify any documents or categories of documents which are expected to contain any exempt information;
7. Disclose any column headers for the data files so that the parties can discuss which columns may need review for potential redactions;
8. Confer with Plaintiff, proactively, about redactions or withholdings that may be needed to expedite that review now and to avoid disputes about redactions post-production;
9. Inform Plaintiff whether Pfizer has already designated information it believes is exempt from disclosure as proprietary trade secrets.

Instead, and only in response to specific prompting from Plaintiff, the agency has provided fractured and incomplete information regarding the volume of the responsive documents, has offered no information about redactions other than the general claim that redactions are needed and take time and resources to apply, and has provided only two tiny limited, piecemeal productions which are useless in isolation. The agency's actions fall far short of due diligence and have already violated its own regulation calling for these precise records to be made "immediately available" after licensure. In fact, the FDA could have performed the basic due diligence needed to provide almost all of foregoing information in less time than it took for it to draft the 19-page declaration filed in this action.

CONCLUSION

The FDA, so focused on its concern for Pfizer's purported trade secrets, simply ignores its obligations to make "immediately available" the requested documents under 21 C.F.R. § 601.51(e) as well as the entire purpose of FOIA – transparency – and its obligation to produce requested documents "as soon as practicable." All of these obligations are frustrated unless the requested documents are produced forthwith. Issues regarding waning immunity, need for boosters, vaccine immunity driving variants, and a host of others, need independent scientists to have transparency into the FDA's process today. Not 75 years from now. And without all the data, a proper analysis of the data cannot be done.

Transparency is also urgently needed here because millions of Americans are being mandated to receive this product under penalty of exclusion from work, school, the military, and everyday life in society. It is unconscionable that the FDA would not immediately assign sufficient personnel or resources to review these documents and release them to the public. It is in fact shocking that the agency did not anticipate this demand for these documents and had not done so prior to Plaintiff's request. Instead, prior to today and since the vaccine was licensed, the FDA has produced a total of 339 pages and two tiny data files. That is an average of producing 3 pages per day since Plaintiff submitted its request on August 27, 2021. Any other documentation released by federal health authorities regarding Pfizer's vaccine were documents generated by the government and were not Pfizer's documents which is what Plaintiff seeks to review. The whole purpose of FOIA and expedited treatment is to review government conduct.

True to form, and despite the passage of 112 days since licensure, the agency incredibly tells the Court in its papers that it still does not know how many pages are in the BLA file for Pfizer's vaccine, can't determine how many rows are in the 126 data files it identified, can't figure out which documents may be easily produced, can't disclose whether the documents were already deidentified by Pfizer, can't provide a full index of the documents, can't determine even how well its existing 10 reviewers can work since two of them are newer, etc. But there are two things the FDA is certain about: it is certain it can ignore the FOIA obligation to produce these documents "as soon as practicable" and it is certain it must put its obligation to redact trade secrets on Pfizer's behalf above the American peoples' right and need to see these documents.

But the FDA seeks to assure the Court that its choice to ignore its disclosure obligations is fine because when it reviewed the Pfizer data the agency "marshaled" all available resources to ensure that the public had access to "life-saving products" as soon as possible. (Dkt. No. 20 ¶ 2.)

That is precisely the issue at hand. The public is entitled to have independent scientists review the data underlying the federal government's decisions regarding this mandatory and liability-free COVID-19 vaccine. The FDA is essentially saying, "trust us, we know what we are doing, no one else needs to check our work." However, Congress made the policy decision decades ago that the American people may trust their government, but they also get to verify that trust through rigorous transparency.

The issue here is simply one of resources and for this issue, the FDA should be directed to produce at least the same speed it took to license the product given the importance of timely production, the obligation to "promptly" produce under FOIA to assure transparency, and the regulation calling for these documents to be "immediately available" to the public following licensure. The FDA should not be above the law. Nor should it be permitted to get away with its unconscionable approach and position with regard to disclosing Pfizer's documents for independent review.

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. Whether the FDA or Pfizer reviews the documents for proposed redactions is not of concern for Plaintiff and should not affect the requested production date of March 3, 2022.

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