IN THE 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

SECOND JOINT REPORT

Plaintiff, Public Health and Medical Professionals for Transparency ("**Plaintiff**"), by and through its attorneys, and Defendant, the U.S. Food and Drug Administration ("**Defendant or "FDA**"), by and through its attorney, hereby submit this Joint Report in compliance with the Court's Order of November 10, 2021, ECF No. 19 (the "**Order**"):

1. The Order asked the parties to "appraise the Court of whether a *scheduling* conference is needed" and if not to "propose[] deadlines for an expedited briefing schedule, if necessary."

2. **Defendant's Position:** A scheduling conference is needed with the Court in order to set a schedule for the processing of records in response to Plaintiff's Freedom of Information Act ("FOIA") request. Setting a processing schedule does not go to the merits of the case, but instead sets the schedule for the necessary deadlines to govern a FOIA case. The processing schedule serves as an important precursor to future deadlines in the case, including scheduling for dispositive motions.

In FOIA cases, a FOIA requestor typically files suit after it has submitted a FOIA request to an agency and the agency has not yet processed and produced all responsive records to the

requestor. 5 U.S.C. § 552(a)(4)(B). Once a case is filed and the government has answered the complaint, the parties usually negotiate a schedule by which the government will search for, process, and produce records responsive to the plaintiff's FOIA request. If the parties are unable to agree upon a schedule, courts typically enter a processing schedule after considering arguments for each party's proposed schedule that were presented in a status report or at a scheduling conference.

A processing schedule is necessary because many different types of information are exempt from the FOIA, such that the government must redact that information before providing responsive records to the plaintiff. *See* 5 U.S.C. § 552(b)(1)–(b)(9). Reviewing and redacting records for exempt information is a time-consuming process that often requires government information specialists to review each page line-by-line. When a party requests a large amount of records, like Plaintiff did here, courts typically set a schedule whereby the processing and production of the non-exempt portions of records is made on a rolling basis.

After the government has completed processing and producing the non-exempt portions of responsive records to the plaintiff, the parties typically confer as to whether the plaintiff intends to challenge the adequacy of the government's search for records or any of the redactions taken to protect the disclosure of exempt material. If the parties have a dispute over the search or the exemptions, the parties typically confer and propose a schedule for summary judgment briefing. Setting a summary judgment schedule before the completion of the production of records is inefficient for the parties and the Court, as it results in piecemeal briefing and consideration of the

merits of the case. Summary judgment briefing in a FOIA case is not the appropriate vehicle to set a schedule for the release of records.[1]

In this case, FDA has assessed that there are more than 329,000 pages potentially responsive to Plaintiff's FOIA request. (This page count is under-inclusive of the material responsive to the request, as it does not include certain types of records that cannot be meaningfully paginated, such as data captured in spreadsheets that contain thousands of rows of data.) The parties have conferred in good faith concerning a processing schedule, but have been unable to reach agreement for the reasons set forth in the parties' Joint Report. *See* ECF No. 18.

Defendant respectfully requests a scheduling conference with the Court for the Court to set a schedule for the processing of documents. Defendant proposed a processing schedule in the Joint Report and resubmits it here for ease of reference. FDA proposes to process and produce the non-exempt portions of the following records by the following dates:

- November 17:
    - From Section 5.2 of the Biologics License Application ("BLA") file:
        - The Tabular Listing
        - The Listing of Clinical Sites
    - The Reports of Postmarketing Experience from Section 5.3.6 of the BLA file
    - One SAS file.[2]

[1] Nor is establishing a briefing schedule for "expedited production" necessary. Any production schedule established as part of a scheduling conference with the Court will inherently resolve any questions related to the rate of the agency's production.

[2] Plaintiff has requested to receive the SAS files in their native format. FDA customarily converts SAS files to PDF files because PDFs can be redacted to prevent the release of non-exempt information. However, FDA is willing to produce SAS files to Plaintiff (if it is feasible for FDA to do so) with the parties' understanding that FDA may have to delete, rather than redact, exempt information from those files to prevent disclosure of exempted information.

- December 1: remainder of section 5.2 of the BLA file.

After the December 1 production, FDA proposes to work through the list of documents that Plaintiff requested FDA prioritize for production in order of priority and process and release the non-exempt portions of those records to Plaintiff on a rolling basis. FDA proposes to process and produce the non-exempt portions of responsive records at a rate of 500 pages per month. This rate is consistent with processing schedules entered by courts across the country in FOIA cases.[3]

Plaintiff's request (as set forth below) that FDA process and produce the non-exempt portions of more than 329,000 pages in four months would force FDA to process more than 80,000 pages per month. Undersigned counsel is not aware of any court *ever* granting such a request. The Court should decline to enter Plaintiff's schedule for numerous reasons.

First, "[r]equiring the agency to process and produce these materials under an abbreviated deadline raises a significant risk of inadvertent disclosure of records properly subject to exemption under FOIA." *Daily Caller v. Dep't of State*, 152 F. Supp. 3d 1, 14 (D.D.C. 2015). Plaintiff has requested records that comprise information submitted by the vaccine sponsor (Pfizer-BioNTech). From FDA's experience with other FOIA requests, such records can be expected to contain both

[3] *See, e.g.*, *Documented NY v. U.S. Dep't of State*, No. 20 Civ. 1946 (AJN) (S.D.N.Y.) Dkt. 26 p.2 (denying plaintiff's processing rate demand of 2,500 pages per month and adopting Department of State's proposed 300 pages per month); *NYCLU v. Admin. for Children & Families*, No. 20 Civ. 183 (MKV), Dkt. No. 30 (S.D.N.Y. May 5, 2020) (400 pages per month); *Color of Change v. U.S. Dep't of Homeland Sec.*, 325 F. Supp. 3d 447, 451 (S.D.N.Y. 2018) (500 pages per month); *Davis v. U.S. Dep't of Homeland Sec.*, No. 11-cv-203 (ARR) (VMS), 2013 WL 3288418, at *1 (E.D.N.Y. June 27, 2013) (500 pages per month); *Blakeney v. FBI*, No. 17-cv-2288 (BAH), 2019 WL 450678, at *2 (D.D.C. Feb. 5, 2019) (500 pages per month); *Colbert v. FBI*, No. 16 Civ. 1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (500 pages per month); *Republican Nat'l Comm. v. U.S. Dep't of State*, No. 16 Civ. 486 (JEB), 2016 WL 9244625, at *1 (D.D.C. Sept. 16, 2016) (500 pages per month); *Energy & Env't Legal Inst. v. U.S. Dep't of State*, No. 17 Civ. 340 (D.D.C.), Minute Order of August 22, 2017 (300 pages per month); *Judicial Watch, Inc. v. U.S. Dep't of State*, No. 17 Civ. 205 (D.D.C.), Minute Order of June 30, 2017 (300 pages every four weeks); *Am. Ctr. for Law & Justice v. U.S. Dep't of State*, No. 16 Civ. 2516 (D.D.C.), Minute Order of June 27, 2017 (process 400 pages per month); *Citizens United v. U.S. Dep't of State*, No. 16 Civ. 67 (D.D.C.), Dkt. 17 at 3 (declining "to adopt Plaintiff's proposed production order of 2000 pages per month" and instead holding State "to its 300-page commitment"); *Freedom Watch v. Bureau of Land Mgmt.*, No. 16 Civ. 2320 (D.D.C.), Minute Order of June 13, 2017 (500 pages every 30 days); *Citizens United v. U.S. Dep't of State*, No. 15 Civ. 1720 (D.D.C.), Dkt. 11 ¶ 10 (500 pages every four weeks); *Judicial Watch, Inc. v. U.S. Dep't of State*, No. 15 Civ. 687 (D.D.C.), Minute Order of April 4, 2017 (500 pages per month).

confidential business and trade secret information of Pfizer or BioNTech and personal privacy information of patients who participated in clinical trials. FDA is required to protect certain information under the law and this type of information is exempt from production under the FOIA. *See* 5 U.S.C. § 552(b)(4), (b)(6); *F.B.I. v. Abramson*, 456 U.S. 615, 621 (1982) ("Congress realized that legitimate governmental and private interests could be harmed by release of certain types of information and provided nine specific exemptions under which disclosure could be refused."). To ensure protection of this information, and other information subject to withholding under the FOIA exemptions, FDA must carefully review and, if necessary, redact exempt information on a line-by-line basis. *See Daily Caller*, 152 F. Supp. 3d at 14 (stating that the government has a "responsibility" when processing FOIA requests to "safeguard[] potentially sensitive information"). This type of review for more than 329,000 pages will necessarily require time if the agency is going to be able to perform the careful analysis necessary to protect sensitive information.

Second, the FDA does not have the personnel or resources in its FOIA office to process Plaintiff's FOIA request at a rate of more than 80,000 pages per month. Plaintiff's FOIA request is being processed by the Access Litigation and Freedom of Information Branch (the "Branch") in FDA's Center for Biologics Evaluation and Research ("CBER"). The Branch has a total of ten employees, including the director and two trainees. It is currently responsible for processing a total of approximately 400 currently pending FOIA requests, including Plaintiff's. CBER is currently involved in 6 active FOIA litigation matters. By processing and making interim responses based on 500-page increments, FDA will be able to provide more pages to more requesters, thus avoiding a system where a few large requests monopolize finite processing resources and where fewer requesters' requests are being fulfilled. Simply put, processing

resources are finite. Increasing the volume to more than 80,000 pages per month (if such rate is even possible – and it likely is not), as Plaintiff requests, would result in Plaintiff monopolizing essentially all of FDA's resources and leaving little resources to process other FOIA requests. Indeed, the D.C. Circuit has recognized that another agency's policy of processing 500 pages per request per month "serves to promote efficient responses to a larger number of requesters." *Nat'l Sec. Counselors v. Dep't of Justice*, 848 F.3d 467, 471–72 (D.C. Cir. 2017); *see also Elec. Privacy Info. Ctr. v. Dep't of Justice*, 15 F. Supp. 3d 32, 47 (D.D.C. 2014) (denying motion for preliminary injunction requesting immediate production of documents pursuant to FOIA request and noting that allowing the plaintiff "to jump to the head of the line would upset the agency's processes and be detrimental to the other expedited requesters"); *Daily Caller*, 152 F. Supp. 3d at 14 (stating that "the plaintiff's effort to jump to the head of the FOIA processing line would work a significant burden on both the agency and numerous interested parties").

Third, the Court should flatly reject Plaintiff's specious argument that because the scientists reviewing Pfizer's Biologics License Application could do so on an expedited timeframe, the government information specialists should be able to do so in the same period of time. As should be apparent, the review conducted by FDA scientists when considering to approve a product is entirely different from the review conducted by FDA government information specialists when considering whether FDA must keep certain information confidential. Moreover, FDA's FOIA office does not have nearly the same level of personnel or resources dedicated to process FOIA requests as FDA has marshaled to review license applications for live-saving products in the middle of a pandemic.

Fourth, contrary to Plaintiff's argument, FDA's regulations do not require or suggest that FDA will release all publicly releasable data immediately after a biologics license application is

approved. When read in context, it is clear that FDA's regulations establish when information in a biological product file is held in strict confidence by the agency and when certain data can be released to the public, for instance in response to standard processing of a request submitted under the Freedom of Information Act. *See generally* 21 C.F.R. § 601.51. Put another way, the regulations establish the point in time when records that may previously have been unavailable for public disclosure lose their status as confidential and thus become available for public release "immediately" upon occurrence of the triggering event. Specifically, under 21 C.F.R. § 601.51, the existence of a biological product file will not be disclosed by FDA prior to BLA approval unless it has been previously disclosed or acknowledged, and no data or information in that file is available for public disclosure. 21 C.F.R. § 601.51(b, c). If the existence of the biological product file has been acknowledged before a license has been issued, FDA generally still will not make information and data in the file available for public disclosure prior to issuance of a BLA license. 21 C.F.R. § 601.51(d). Once a license has been issued, however, certain data and information in the biological product file become "immediately" available for public disclosure. 21 C.F.R. § 601.51(e). That means that if a properly submitted FOIA request is received for data and information listed in 21 C.F.R. § 601.51(e), FDA may publicly release such information in response to such request, without need for additional agency action to reclassify as publicly releasable data and information that had previously been deemed confidential under this regulation.

Fifth, although Plaintiff takes issue with the amount of time it will take to process 329,000 pages at a rate of 500 pages per month, such a result is due to its own broad FOIA request. Courts do not waiver from the standard 500 page per month processing rate even when a FOIA request would take years to process. *See, e.g.*, *Colbert v. F.B.I.*, No. 16-CV-1790 (DLF), 2018 WL

6299966, at *3 (D.D.C. Sept. 3, 2018) (permitting a processing rate of 500 pages per month for 71,000 responsive records). FDA has invited Plaintiff to narrow its request by specifying records it no longer wants FDA to process and release, and Plaintiff has declined to do so. If Plaintiff decides to request fewer records, then FDA will be able to complete its processing at an earlier date.

Finally, this case is not about a vaccine mandate or whether Pfizer can be held liable. This is a FOIA case where the only relevant issue at this stage in the litigation is setting a reasonable processing schedule. FDA's proposed schedule of 500 pages per month is consistent with schedules set by courts across the country, including in cases where the underlying records were of national significance. It adequately balances the interests of the Plaintiff in responsive records with the interests of the vaccine sponsor in the protection of its confidential information, the interests of clinical trial participants in the protection of their personal privacy information, and the interests of other FOIA requesters whose requests are being processed alongside Plaintiff's.

3. **Plaintiff's Position:** Plaintiff agrees with the Defendant's position that the Court may enter a production schedule based on the arguments in this Joint Report or do so at a conference. Plaintiff seeks the records submitted to the FDA by Pfizer to license its COVID-19 vaccine (the "**FOIA request**")[4] and requests an order requiring the FDA to produce all documents

[4] The FOIA request requested: "All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[4] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[4]" The CFR provision referenced in the FOIA request provides, in relevant part, as follows: "After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . (3) Adverse reaction reports. . . (4) A list of all active ingredients and any inactive ingredients . . . (5) An assay method or other analytical method . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . (7) All records showing the manufacturer's testing of a particular lot . . . (8) All records showing the testing of and action on a particular lot by the [FDA]." The FOIA request also explained that "For the avoidance of doubt, the FOIA Request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the 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."

responsive to its FOIA request no later than March 3, 2022. This 108-day period 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 (the "**Pfizer** v**accine**").

Plaintiff is an organization comprised of over 30 accomplished academics, professors, and scientists from the medical schools and related departments of our most prestigious universities, including Yale, Harvard, UCLA, and Brown. These academics and scientists represent a cross section of every discipline relevant to the licensure of the Pfizer vaccine and include many of the best our country has to offer when it comes to reviewing and assessing the appropriateness and validity of the FDA's decision-making in licensing this product.

The ability of a majority of Americans to participate in civil society, and even exercise basic liberty rights, are now contingent on receiving this product. For example, the White House's recent Covid-19 Action Plan[5] and executive orders[6] have made receipt of this product a condition of employment[7] for more than 6 million federal workers and contractors,[8] 22 million healthcare professionals,[9] 84 million private sector employees,[10] and the enlisted and reserve members of our

[5] https://www.whitehouse.gov/covidplan/#testing-masking (last visited November 15, 2021).

[6] *See* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/ (Executive Order of Ensuring Adequate COVID Safety Protocols for Federal Contractors) (last visited November 15, 2021); https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/ (Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees) (last visited November 15, 2021).

[7] *See, e.g.*, https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.501 (Emergency Temporary Standard requiring employers with 100 or more employees to implement vaccination mandates) (last visited November 12, 2021); https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/ (Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees) (last visited November 12, 2021).

[8] https://thehill.com/opinion/finance/438242-the-federal-government-is-the-largest-employer-in-the-nation (last visited November 12, 2021).

[9] https://www.census.gov/library/stories/2021/04/who-are-our-health-care-workers.html#:~:text=There%20were%2022%20million%20workers,American%20Community%20Survey%20(ACS) (last visited November 12, 2021).

[10] https://www.cnbc.com/2021/11/04/osha-federal-vaccine-mandate-covers-84-million-workerswhat-to-know.html (last visited November 12, 2021).

armed forces.[11] There are few whose livelihood, education, service, and participation in civil society are not contingent on a government requirement to receive this product. On this basis alone, basic liberty and government transparency demand that the documents and data submitted by Pfizer to license this product be made available to Plaintiff and the public forthwith, precisely as contemplated by federal regulations.[12]

The acute need for transparency regarding this product is heightened by the fact that the secretary of Health and Human Services ("**HHS**"), the FDA's parent department, has granted Pfizer complete immunity from financial liability for any injury caused by its product. If injured -- including suffering one of the injuries even federal health authorities admit occur from Pfizer's product -- the injured individual effectively has no recourse. Pursuant to the declaration from the secretary of HHS, Pfizer cannot be sued by anyone receiving this product for any injury. 42 U.S.C. § 247d-6d. Pfizer also cannot be sued for willful misconduct regarding this product unless HHS, which has been promoting this product, agrees to bring such a claim. 42 U.S.C. § 247d-6d(c)(5).[13] It should not be that the public is deprived accessing the documents and data submitted by Pfizer to license this product when at the same time the public are being mandated to receive this product with no ability to sue Pfizer for compensation if they suffer any adverse reaction.

The FDA has proposed to produce 500 pages per month which, based on its calculated number of pages, would mean it would complete its production in nearly 55 years – the year 2076. Until the entire body of documents provided by Pfizer to the FDA are made available, an

[11] https://www.americaspromise.org/us-military-demographics#:~:text=Military%20Service%20Member%20Data,were%202.1%20active%20duty%20members (last visited November 12, 2021).

[12] *See* 21 CFR § 601.51(e).

[13] Reports have recently surfaced that the FDA was aware of concerns about unsound practices in connection with clinical trials for the Pfizer Vaccine, but that FDA failed to properly investigate these claims. https://www.bmj.com/content/375/bmj.n2635 (last visited November 12, 2021).

appropriate analysis by the independent scientists that are members of Plaintiff is not possible. Would the FDA agree to review and license this product without all the documents? Of course not. These independent, world-renowned scientists should be provided the same forthwith.

The entire purpose of the FOIA is to assure government transparency. It is difficult to imagine a greater need for transparency than immediate disclosure of the documents relied upon by the FDA to license a product that is now being mandated to over 100 million Americans under penalty of losing their careers, their income, their military service status, and far worse.

It took the FDA precisely 108 days from when Pfizer started producing the records for licensure on May 7, 2021,[14] to when the product was licensed on August 23, 2021.[15] We assume, as the FDA has stated, that it conducted an intense, robust, thorough and complete review and analysis of those documents in order to assure that the Pfizer vaccine was safe and effective for licensure. The FDA now has an equally important task of making those documents available to the Plaintiff in this case and the public at large in at least the same timeframe.

The FDA's own regulations envision and reflect upon the importance of making this information public as soon as a vaccine is licensed. Its regulations provide that it is to make "immediately available" all documents underlying licensure of a vaccine. 21 C.F.R. § 601.51(e). The FDA knew the intense public interest in that data and information. It should have been preparing to release it simultaneously with the licensure. Instead, it has done the opposite. Despite the passage of 84 days since licensure and 192 days since Pfizer started producing the records for

[14] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics (Pfizer announces that it initiated rolling submission of its biologics license application on May 7, 2021) (last visited November 12, 2021).

[15] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (FDA announces that it approved Pfizer's COVID-19 vaccine on August 23, 2021) (last visited November 12, 2021).

licensure, the FDA has not released a single document submitted by Pfizer for the licensure of its Covid-19 vaccine. Not one page.

Mandates of this liability-free product are ongoing and expanding as we debate in this Joint Report. School-age children are now being mandated to take this product.[16] Even 108 days from today to produce is far too long, hence Plaintiff respectfully urges that March 3, 2022 be set as the absolute outside date by which the FDA be compelled to produce these documents. The FDA is an organization comprised of more than 18,000 people[17] with a budget of $6 billion.[18] It has itself said that there is nothing more important than the licensure of this vaccine and being transparent about this vaccine. This request is precisely why the need for transparency is so critical and why Congress enacted FOIA. If the FDA claims its obligations under FOIA are too burdensome, it should take its complaints to Congress – not this Court.

For the Americans that will lose their job, income, career, military status, education, or worse, for refusing a federal mandate requiring this product, they do not get to argue that it is too burdensome to comply with federal law. That is not an excuse that individuals get to make when a federal law requires them to do something. The FDA should similarly be afforded no such safe harbor. Certainly not on an issue this important. Again, if the FDA finds complying with federal law burdensome, its recourse is with Congress.

In any event, the FDA should welcome making these documents available to the Plaintiff if it is confident in the analysis and review it conducted. The fact that it has fought tooth and nail

[16] *See*, e.g., https://www.nbcsandiego.com/news/local/san-diego-unified-school-district-vaccine-mandate/2729909/.

[17] https://www.fda.gov/about-fda/fda-basics/how-many-people-are-employed-fda-and-what-areas-do-they-work (last visited November 12, 2021).

[18] https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited November 12, 2021).

and taken such an absurd and unconscionable position of waiting until the year 2076 to complete the production further heightens the grave need to have these documents produced forthwith.

Plaintiff respectfully requests that the Court enter an order requiring the FDA to produce all documents and data submitted by Pfizer on a rolling basis such that all of it shall be produced on or before March 3, 2022, which is 108 days from today. To require less is to render FOIA meaningless, the FDA's promise of transparency a lie, and to send a signal to every American that while the federal executive branch is shielding Pfizer from any liability for injuries from its product and requiring employers, schools, hospitals and the military to expel those that don't receive this product, it is protecting the very documents Pfizer provided to our taxpayer-funded health agency to obtain licensure to be able to sell this product. That simply should not be and highlights why FOIA and equity demand the relief Plaintiff requests herein.

Dated: November 15, 2021

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