IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

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

DEFENDANT'S REPLY BRIEF IN ADVANCE OF SCHEDULING CONFERENCE

INTRODUCTION

This is a Freedom of Information Act ("FOIA") case; it is not a challenge to the decision of the U.S. Food and Drug Administration ("FDA") to approve Pfizer's COVID-19 vaccine, and it is not about either the legality or the wisdom of vaccination mandates. Nor is this case about the Federal Government's grant of legal immunity to Pfizer and other producers of related vaccines.[1] Indeed, none of these topics—to which Plaintiff Public Health and Medical Professionals for Transparency ("PHMPT") devotes much if not most of its "Brief in Support of

[1] Although wholly legally irrelevant to the issue before the Court, Plaintiff's repeated insinuations that there is anything remarkable or unusual about the legal immunity afforded to Pfizer and other manufacturers of similar COVID-19 vaccines is false. *See, e.g.*, https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters (homepage of the Office of Special Masters, U.S. Court of Federal Claims, which administers the National Vaccine Injury Compensation Program ("Vaccine Program")).

Timely Production" (Plaintiff's "First Brief," or "Pl. Br."), Dkt. No. 26[2]—has any real legal relevance to the straightforward issue before the court: *i.e.*, what rate is reasonable and feasible for the processing of records responsive to Plaintiff's FOIA request, taking into account, *inter alia*, the breadth of the request, FDA's mushrooming FOIA docket, applicable resource constraints, and fairness to other FOIA requesters.

Nor is the issue of expedition really at issue. As explained herein, FDA correctly determined that—particularly in light of the copious information that FDA and other federal agencies have already made public regarding the Pfizer vaccine—Plaintiff is not entitled to expedition under the applicable standards established by FOIA and agency regulations. However, and in any event, FDA has started processing Plaintiff's request—and, thus, Plaintiff has already received all the relief that expedition affords, rendering this issue moot. Moreover, even where formal expedition is granted, FOIA does not mandate any particular processing schedule, but rather only that the agency process responsive records "as soon as practicable." 5 U.S.C. § 552(a)(6)(E)(iii). Thus, even in expedited cases, the bottom-line issue still remains what processing schedule is "practicable" for the agency.

The processing schedule demanded by Plaintiff—that FDA process approximately 329,000 record in a matter of mere *months*—not only fails to meet that standard by any arguable stretch of the imagination, but is simply not possible for FDA to meet. Conversely, FDA is making every effort to process Plaintiff's request as quickly as "practicable"—an effort that is reflected by both the some 3,000-plus pages that Plaintiff will have received prior to the Court's scheduling conference, as well as the 12,000-plus pages that FDA proposes to produce by the

[2] Defendant's reply responds to Plaintiffs "corrected" brief, filed December 7, 2021. *See* Dkt. No. 26.

end of January 2022. While FDA cannot at this juncture commit to a processing schedule in excess of 500 pages per month beyond that point, FDA's proposal reflects a floor, not a ceiling; if FDA is thereafter able to process records at a faster pace, its proposal commits it to do so.

Accordingly, to the extent that the Court declines to adopt FDA's proposal in full, the agency respectfully requests that the Court partially adopt its proposal now—*i.e.*, approve FDA's proposal for the production of more than 12,000 pages by January 31, 2022—and then revisit the issue of a longer-term processing and production schedule with both parties in February 2022. That approach would afford Plaintiff time to assess how it might productively narrow its request; afford FDA more time to assess whether faster processing may be possible for at least certain subsets of the responsive records; and also afford both parties more time to use their best efforts to negotiate a mutually agreeable processing schedule. In the meantime, the partial adoption of FDA's proposal will ensure that the agency maintains a full-court press ahead, while adequately protecting numerous important public interests.

DEFENDANT'S INTERIM DECEMBER 13, 2021 PRODUCTION

Before turning to the substance of the issues currently presented by this matter, Defendant briefly confirms that on December 13, 2021—*i.e.*, the same day this filing is being made—it will make the production specified by its proposed processing schedule. *See* Defendant's Brief in Advance of Scheduling Conference ("Def. Br."), Dkt. No. 22, at 7-8. That is, before the end of the day today, Defendant will make the production described below, consisting of approximately 2,900 additional pages, as well as 9 additional files:

- Plaintiff's priority item #1 – CRF files for site 1055 (approximately 2,030 pages);
- Completion of Plaintiff's priority item #5 –
    - Four additional .txt files that were listed on pages 10 and 11 of the Index;

  - Five additional SAS files (not specifically listed on Plaintiff's priority list, but Plaintiff has expressed interest in these files during the course of negotiations).

- Publicly releasable information from the following additional sections of the original Comirnaty BLA:

  - Section 2.5 – Clinical Overview (approximately 333 pages)

  - Section 2.7.3 – Summary of Clinical Efficacy (approximately 182 pages)

  - Section 2.7.4 – Summary of Clinical Safety (approximately 344 pages)

Thus, by the time of the Court's scheduled status conference, FDA anticipates that it will have produced to Plaintiff more than 3,000 pages of responsive materials, most of which were listed on Plaintiff's Priority List. Moreover, FDA will have completed processing and production of four items on Plaintiff's Priority List (items 1, 5, 6, and 8).

ARGUMENT

I. Plaintiff Has Not Demonstrated an Entitlement to Expedited Processing, and Expedition Is In Any Event Moot

Defendant's prior filings explain the relevant legal framework established by FOIA for the processing and production of federal records under that Act's auspices. *See* Def. Br. 1-2; Dkt. No. 20 at 1-3. Defendant respectfully refers the Court those earlier filings, and will not repeat that framework at length here. In short, when a plaintiff brings a FOIA lawsuit, it is common for the parties to confer and agree upon—or, where agreement is not possible, for the Court to adjudicate—a reasonable schedule by which the defendant agency will search for, and then process in comportment with FOIA's enumerated exemptions, records responsive to the plaintiff's FOIA request. This is the stage that the instant case has reached, and thus the issue now before the Court.

Although FOIA allows—in exceptional circumstances where requesters meet the stringent regulatory requirements—for an agency to prioritize certain requests for expedited

processing, Plaintiff did not justify such treatment before FDA, and has not properly presented such a claim before the Court. Indeed, Plaintiff's Complaint does not plead a claim for expedited processing, and thus this issue is not properly before the Court at all. *Cf. New York Times Co. v. Def. Health Agency*, No. 21-CV-566 (BAH), 2021 WL 1614817, at *4 (D.D.C. Apr. 25, 2021) (noting that the question of whether the plaintiff had "met the requirements for expedited processing," was "not properly before" the court, where the "plaintiff assert[ed] no claim challenging the agencies' explicit or constructive denial of expedited processing in the Complaint"). Moreover, as Defendant explains in detail below, judicial review of an agency's denial of an expedition request is on "the record before the agency at the time of the determination," 5 U.S.C. § 552(a)(6)(E)(iii), much like a claim brought under the Administrative Procedures Act ("APA"). Thus, to the extent, *arguendo*, that the Court were to excuse Plaintiff's non-compliance with Federal Rule of Civil Procedure 8 and take up the merits of an unpled expedition "claim" at the forthcoming scheduling conference, the Court is statutorily precluded from considering, *inter alia*, any of the declarations submitted by Plaintiffs—none of which was before FDA at the time of its administrative decision. In any event, FDA correctly assessed that Plaintiff's request does not satisfy the requisite standards for expedition, and its decision, to the extent it is reached, should be affirmed.

Finally, for all practical purposes, expedition is moot in any event. Expedition only entitles the requester to move to the top of the processing queue, ahead of non-expedited requests and behind earlier granted expedited requests. FDA has already started to process Plaintiff's request, however, which is the most relief Plaintiff can receive from a grant of expedition. Once expedited, the agency is required to process the request as soon as "practicable." What is practical here is the essential issue before the Court.

A. Applicable Legal Framework for Requests for Expedited Processing

Agencies ordinarily process FOIA requests for agency records on a first-in, first-out basis. In 1996, Congress amended the FOIA to provide for "expedited processing" of certain categories of requests. *See* Electronic Freedom of Information Act Amendments of 1996, Pub. L. No. 104-231, § 8, 110 Stat. 3048 (codified at 5 U.S.C. § 552(a)(6)(E)) ("EFOIA"). Expedition, when granted, entitles requestors to move immediately to the front of an agency processing queue, ahead of requests filed previously by other persons not granted expedited processing themselves.

As part of EFOIA, Congress directed agencies to promulgate regulations providing for expedited processing of requests for records. Specifically, Congress directed agencies to enact regulations providing for expedited processing (i) "in cases in which the person requesting the records demonstrates a compelling need," 5 U.S.C. § 552(a)(6)(E)(i)(I); and (ii) "in other cases determined by the agency." *Id.* § 552(a)(6)(E)(i)(II).

FOIA further defines "compelling need" as either (1) "that a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual," or (2) "[w]ith 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." 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II). And, in carrying out FOIA's instruction to further implement these standards via regulation, FDA added the specification that, with respect to the second of these tests, the "urgency" must be "demonstrated." 21 C.F.R. § 20.44(a)(2). Specifically, in order to satisfy 21 C.F.R. § 20.44(a)(2), a FOIA requester must "demonstrate" that:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;

> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly . . . and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

Id. § 20.44(c)(1)-(3).[3]

In enacting EFOIA, Congress specified that the expedited processing categories should be "narrowly applied." *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001) *Al-Fayed*, 254 F.3d at 310 (quoting H.R. Rep. No. 104-795, at 26, 1996 U.S.C.C.A.N. 3448, 3469 (1996(). As the D.C. Circuit has explained,[4]

> Congress' rationale for a narrow application is clear: "Given the finite resources generally available for fulfilling FOIA requests, unduly generous use of the expedited processing procedure would unfairly disadvantage other requestors who do not qualify for its treatment." . . . Indeed, an unduly generous approach would also disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none.

Id. at 307 n.7 (D.C. Cir. 2001) (quoting H.R. Rep. No. 104-795, at 26). Likewise, Department of Justice guidance advises agencies to "carefully" assess the merits of expedited processing requests "[b]ecause the granting of a request for expedition necessarily works to the direct disadvantage of other FOIA requesters." U.S. Department of Justice, FOIA Update: OIP Guidance: When to Expedite FOIA Requests (Jan. 1, 1983), https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

Further, while the burden is on the agency to sustain its action in cases involving the improper withholding of records under claimed FOIA exemptions, 5 U.S.C. § 552(a)(4)(B), the

[3] FDA's regulation does not provide for any other circumstances that qualify for expedition.

[4] Courts often rely on the case law concerning FOIA from the D.C. Circuit, as it is "the federal appellate court with the most experience in this field." *Cameron Corp. v. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

requestor has the burden to "demonstrate[] a compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(i); *see also Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 122 (D.D.C. 2013) (explaining that "[t]he requestor bears the burden of proof" in expedited processing cases); *Al-Fayed*, 254 F.3d at 305 n.4 (same) (citing 5 U.S.C. § 552(a)(6)(E)(i)(I) and H.R. Rep. No. 104-795, at 25).

Finally, expedition decisions are subject to judicial review in accordance with § 552(a)(6)(E)(iii),which states:

> Agency action to deny or affirm denial of a request for expedited processing pursuant to this subparagraph, and failure by an agency to respond in a timely manner to such a request shall be subject to judicial review under [5 U.S.C. § 552(a)(4)], ***except that the judicial review shall be based on the record before the agency at the time of the determination***.

5 U.S.C. § 552(a)(6)(E)(iii) (emphasis added); *see also, e.g., Am. Oversight v. U.S. Dep't of Justice*, 292 F. Supp. 2d 501, 505-06 (D.D.C. 2018). Section 552(a)(4), the cross-referenced provision, is the general FOIA provision authorizing judicial review of agency decisions to withhold records from FOIA requestors. *See id.* § 552(a)(4)(B). A decision denying expedited processing for failure to establish "compelling need" under § 552(a)(6)(E)(i)(I) is reviewed *de novo*. *See Al-Fayed*, 254 F.3d at 307-08.

B. FDA Properly Denied Plaintiff's Request for Expedited Processing

Applying the above-described standards, FDA properly denied Plaintiff's request for expedited processing, and—to the extent the Court reaches the question—it should affirm the agency's decision. In assessing this question, the Court is statutorily limited to "the record before the agency at the time of the determination," 5 U.S.C. § 552(a)(6)(E)(iii)—which, here, excludes each of the supporting declarations submitted by Plaintiff, as well as all of the links and exhibits cited in the Declaration of Aaron Siri, Esq., save for the materials cited in paragraphs 29,

30, 31, 32, 33, 38, and 40 of the declaration. *See, e.g.*, *See, e.g., Nat'l Day Laborer Org. Network v. U.S. Immigr. & Customs Enf't*, 236 F. Supp. 3d 810, 818 (S.D.N.Y. 2017) (declining to consider group's later-submitted declaration because it was not before the agency at time of decision).

After assessing Plaintiff's request for expedition, as well as the supporting media articles cited in its application, FDA determined that, while Plaintiff had demonstrated that it is "primarily engaged in disseminating information to the general public and not merely to a narrow interest group," 21 C.F.R. § 20.44(c)(1), it had not "demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." Ex. D (Declaration of Sarah B. Kotler) (hereinafter "Kotler Decl.") ¶ 20 (App119). Of primary importance, the agency took into account the significant amount of information publicly available through the agency's FOIA reading room, and determined that there was not an urgency to inform the public with respect to the remaining information. Specifically, as explained by the Kotler Declaration, Plaintiffs' administrative application argued, first, that "there was an 'ongoing, public national debate' about FDA's decision to license the Comirnaty vaccine, quoting numerous individuals, including a number of Plaintiff's members, with varying opinions about the vaccine." *Id.* ¶ 19 (App119). And "[s]econd, Plaintiff noted that many organizations had mandated COVID-19 vaccines for their members or employees." *Id.*; *see* Dkt. No. 1-1 (Plaintiff's FOIA request and request for expedition). As the Kotler Declaration explains, after carefully assessing these arguments, and the citations cited in Plaintiff's application, FDA determined that:

> The fact that people may have differing opinions about a certain FDA-regulated product does not create "urgency" within the meaning of the expedited processing standard for the agency to produce an entire BLA – especially in light of the amount of information published on FDA's website. Nor does the fact that certain individuals may be administered a certain product. FDA approves medical products regularly in the course of agency business. It is not unheard of for those

> approvals to be the subject of controversy, and there are almost always people who are administered the products shortly after approval. Such a situation cannot be deemed to create an urgent need for the agency to expedite its review and processing of the hundreds of thousands of pages of records, especially when the agency routinely publishes summaries of safety and efficacy information on its website (as it did here). If Plaintiff's view became the standard, a great number of FDA's FOIA requests would qualify for expedited processing, and requesters with non-expedited requests would have their wait times extended – possibly significantly.

Kotler Decl. ¶ 21 (App120); *see also id.* ¶ 20 (App119) (explaining that in reaching this conclusion, FDA assessed Plaintiff's request against the backdrop of the "significant amount of information related to the Comirnaty vaccine" that FDA is posting to its official website on an ongoing basis—including, but by no means limited to, "FDA review memoranda, which include summaries of safety and effectiveness data, as well as FDA reviewers' analyses of them."); *id.* ¶¶ 11-14, 20 (further describing the ample information regarding the Comirnaty vaccine that FDA—as well as its sister agency, the Centers for Disease Control and Prevention ("CDC")—has voluntarily, and proactively, made publicly available on its website) (App115-17, App119-20).

For much the same reasons set forth in the Kotler Declaration, the Court should likewise deny Plaintiff's request for expedited processing. First, like FDA, the Court should assess this request against the backdrop of the quite substantial amounts of information about the Comirnaty vaccine that FDA and CDC have already made available to the public. Specifically, and as explained in detail in the Kotler Declaration, the FDA has made every effort to make information about the Comirnaty vaccine publicly available quickly through its official website. *See generally* Kotler Decl. ¶¶ 11-14 (App115-17).

With respect to the Pfizer vaccine in particular, the FDA has posted a host of important information on its "Comirnaty and Pfizer-BioNTech COVID-19 Vaccine" page:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty. Kotler Decl. ¶¶ 12, Exh. A (App115-16, App131-38). Materials posted there include, *inter alia*, Frequently Asked Questions for Comirnaty, information sheets for healthcare providers, regulatory information, media materials and webcasts, advisory committee information, and even links to video recordings of virtual meetings of FDA's advisory committee (the Vaccines and Related Biological Products Advisory Committee). *Id.* Further, clicking on the "Comirnaty Information" link on the above page brings the user to yet another page with more information specific to the Comirnaty vaccine: https://www.fda.gov/vaccines-blood-biologics/comirnaty. This page contains a collection of resources that FDA believes are especially useful to members of the public who wish to understand the FDA's approval decision. *Id*. ¶ 13 (App116-17). Documents posted here include the package insert for the vaccine, the Summary Basis for Regulatory Action, FDA's Approval Letter, FDA decision memoranda, and the approval history for the vaccine.[5] *Id.* Currently, FDA's Comirnaty page contains links to approximately *700 pages* of records related to the Comirnaty vaccine licensure. *Id.* These records often contain summaries of the information and data submitted by Pfizer and BioNTech that FDA reviewed and assessed, as well as FDA's assessment, that support FDA's decision to license the Comirnaty vaccine. *Id.* By way just one illustrative example, FDA has posted there the 107-page "BLA Clinical Review Memorandum" for the Corminaty vaccine, available at: https://www.fda.gov/vaccines-blood-

[5] Many of these records were posted shortly after the Comirnaty biological license application ("BLA") was approved on August 23, 2021. For example, FDA posted its "Summary Basis for Regulatory Action" the day after the Comirnaty BLA was approved; it posted the Action Package, including FDA discipline review memos such as clinical, statistical and toxicology reviews, approval letter, and package insert, within 25 days of approval. Kotler Decl. ¶¶ 13 (App116-17).

biologics/comirnaty (under link to "Approval History, Letters, Reviews, and Related Documents – COMIRNATY"). This memorandum includes sections entitled, "Clinical and Regulatory Background," "Submission Quality and Good Clinical Practices," Significant Efficacy/Safety Issues Related to Other Review Disciplines," Discussion of Individual Studies/Clinical Trials," and the FDA reviewers' conclusions and recommendations based on the data reviewed. *See* Kotler Decl. ¶ 13 (App116-17).

Thus, the FDA reasonably assessed that the significant amount of substantive, detailed information on the same topics encompassed by Plaintiff's FOIA request undermined any arguable justification to put Plaintiff's request at front of its processing queue, ahead of the many hundreds of pending requests that pre-dated it. And in light of this quite considerable amount of already publicly available information, this Court should do the same.

Further, the Court should also bear in mind that controversies regarding FDA approvals of biologics and other medical devices are often the subject of substantial controversy, and regardless of subject matter, FDA must handle its substantial volume of FOIA requests equally and fairly. As FDA has stressed throughout these proceedings, any grant of expedition necessarily comes at the expense of other requestors who are pushed back in the queue. Although those requestors are not before the Court in this action, they also have an interest in receiving the documents that they sought *Cf.* 5 U.S.C. § 552(a)(6)(E)(v)(II) (stating that one of the criteria for granting expedited processing for "request[s] made by a person primarily engaged in disseminatinginformation" is "urgency to inform the public"). Granting expedition liberally amounts to no expedition at all. *See Al-Fayed*, 254 F.3d at 307 n.7 (noting that "an unduly generous approach" to expedition requests would "disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none").

In sum, in light of both the substantial amount of information already publicly available regarding the Comirnaty vaccine, as well as the unfairness that special treatment of Plaintiff's request would work on other FOIA requesters, the Court should uphold FDA's decision to deny the expedition request.

II. Plaintiff Has Already Received all the Relief Expedition Affords Because FDA Has Started Processing Plaintiff's Request and is Proceeding as Fast As Practicable.

In any event, even if Plaintiff's FOIA received expedited treatment, Plaintiff is not entitled to an order requiring production of all responsive, non-exempt records by March 3, 2022. Even in cases of expedited FOIA processing, "[t]he statute does not assign any particular time frame to release of the records sought." *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 275 (D.D.C. 2012). Rather, the statute directs an agency to "process as soon as practicable any request for records to which the agency has granted expedited processing." 5 U.S.C. § 552(a)(6)(E)(iii); *see also, e.g.*, *Muttitt v. Dep't of State*, 926 F. Supp. 2d 284, 296 (D.D.C. 2013) ("the only relief required by the FOIA with regard to expedited processing is moving an individual's request 'to the front of the agency's processing queue'"). Indeed, expedited consideration entitles requesters to move immediately to the front of the applicable processing queue, but *not* ahead of all other requests that have already been granted expedited processing. A Senate Judiciary Committee report explained the expedited processing provisions as follows:

> Once . . . the request for expedited access is granted, the agency must then proceed to process that request "as soon as practicable." No specific number of days for compliance is imposed by the bill since, depending upon the complexity of the request, the time needed for compliance may vary. The goal is not to get the request for expedited access processed within a specific time frame, but to give the request priority for processing more quickly than otherwise would occur.

EFOIA, S. Rep. No. 104-272, at 17 (1996), *available at* 1996 WL 262861.

Thus, even in cases where expedited processing is granted, courts evaluate whether the

processing schedule is practicable in light of other expedited FOIA requests the agency was already processing, the volume of materials, the need for agency review, and competing obligations of the same agency staffers. *See Elec. Privacy Info. Ctr. ("EPIC") v. DOJ*, 15 F. Supp. 3d 32, 43 (D.D.C. 2014). It follows that, even if, *arguendo*, the Court were to determine that Plaintiff's FOIA request is entitled to expedited treatment, the bottom-line issue still remains what processing schedule is "practicable" for FDA. For several reasons, Plaintiff's proposed schedule is not only impracticable, but well outside the realm of reason. Moreover, Plaintiff itself bears the sole responsibility for the enormously broad scope of its request; to the extent it is dissatisfied with the speed at which FDA is able to process the more than 300,000 pages encompassed by the request, Plaintiff can narrow its request and focus its terms to a more manageable set of documents. *Cf. Am. Ctr. for Law & Justice v. U.S. Dep't of Homeland Sec.*, No. 1:21-CV-01364 (TNM), --- F.3d ---, 2021 WL 5231939, at *5 (D.D.C. Nov. 10, 2021) (dismissing overly broad request and noting that, due to certain unintended incentives created by FOIA, requesters often, and perversely, have "everything to gain and little to lose from posing broad, complicated FOIA requests," which has, in turn, engendered substantial FOIA backlogs across the federal government). Conversely, FDA's proposal—which Plaintiff badly and hyperbolically mischaracterizes—properly balances the many competing interests at stake, and will conclude processing and production within the shortest period of time that is both reasonable and feasible.

A. 21 C.F.R. § 601.51 Does Not Contemplate the Immediate or Automatic Publication of the Records Sought by Plaintiff

As a threshold matter, Plaintiff repeatedly mischaracterizes FDA's regulations.[6]

[6] *See* Pl. Br. at 11, 13, 15, 25; *see also* First Joint Report, Dkt. No. 18, at 2, 5; Second Joint Report, Dkt. No. 22, at 11.

Plaintiff's FOIA request seeks "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." Burk Decl. ¶ 24 (App011). According to Plaintiff, Section 601.51(e) directs FDA to "immediately" publish the categories of data and information it enumerates, upon the issuance of a license for a new biological product. Section 601.51(e) does no such thing, nor is it reasonably susceptible to Plaintiff's erroneous construction.

Section 601.51 generally provides for FDA's treatment of information in a biological product file, throughout the "lifecycle" of the biologics license application ("BLA") to which the biological product file corresponds. Information related to the development of a new biological product is of great commercial sensitivity, and pursuant to this regulation, FDA does not disclose such information unless and until the biological product is approved. Thus, while a BLA remains pending before FDA, its corresponding biological product file is, pursuant to Section 601.51, effectively a black box.[7]

"After a license [for a biological product] has been issued," however, Section 601.51(e) provides that several enumerated categories of information within the biological product file lose their regulatory confidentiality and become "immediately *available* for public disclosure." 21 C.F.R. § 601.51(e)(1)-(8) (listing the applicable categories of data and information) (emphasis added). Contrary to Plaintiff's repeated mischaracterization of the plain meaning of this provision, however, Section 601.51(e) does not require FDA to immediately "publish" such

[7] Specifically, prior to the approval of a given BLA, FDA will not disclose even the mere *existence* of the BLA "unless it has previously been publicly disclosed or acknowledged," nor will FDA disclose any "data or information in the biological product file." 21 C.F.R. § 601.51(b), (c). And even where the existence of a biological product file is "publicly disclosed or acknowledged before a license has been issued," FDA will not disclose any "data or information contained in the file," outside narrow circumstances not relevant here. *Id.* § 601.51(d)(1).

information. Rather, by operation of this provision, the specified categories of data and information lose their across-the-board confidentiality protections, such that they are now *available*—just like any other public record within the parameters of FOIA—for public disclosure, upon request. But—and again, just like any other public record within the parameters of FOIA— records that may include information and data listed in Section 601.51(e) must be carefully reviewed to determine whether one or more FOIA exemptions apply. Indeed, Plaintiff does not contend otherwise. That a disclosure review is necessary is apparent from the text of 21 C.F.R. § 601.51(e) itself, which limits disclosure of several types of information if such information falls within certain categories protected by FDA's regulations. *See* 21 C.F.R. §§ 601.51(e)(2), (3), (5), (6), (7). Further, the regulation expressly states that certain other types of information in the biological product file for an approved BLA are not available for public disclosure. 21 C.F.R. § 601.51(f). Because the categories of information not available for public disclosure under 21 C.F.R. § 601.51(f) or subject to withholding under 21 C.F.R. §§ 601.51(e)(2), (3), (5), (6), (7) can be intermingled with the types of information available for disclosure under 21 C.F.R. § 601.51(e), a disclosure review is essential.

And, as discussed at length in other filings and herein, the processing of records subject to FOIA, like any other kind of work, necessarily takes time and simply cannot be performed "immediately," Plaintiff's contentions notwithstanding. Thus, while Section 601.51(e) certainly embodies the principle of transparency—to which FDA is strongly committed—it neither directs, nor even permits, FDA to simply publish the specified categories of data and information without conducting the careful (and time-and-resource-intensive) disclosure review that Defendants have described in detail throughout these proceedings.

B. FDA Cannot Re-Assign Untrained and Unqualified Personnel with Other, Crucial Programmatic Duties to Process Plaintiff's FOIA Request

Plaintiff's suggestion that FDA may meet its extraordinary demand to process in excess of 300,000 pages of responsive documents in a matter of mere months by "simply" re-assigning its personnel to is likewise misguided. As the Kotler Declaration explains:

> First, performing disclosure reviews is a specialized skill that requires training and expertise that the vast majority of FDA staff does not have. It is not reasonable to expect that a microbiologist who performs laboratory assays, a pharmacist who reviews drug applications, a badging office employee who issues credentials, or a mail room clerk who organizes mail can simply begin performing disclosure review without significant training. Moreover, it would be contrary to FDA's public health mission to pull staff off reviewing cancer treatment applications or building counterfeit medication investigations to have them conduct work for which they are untrained and unqualified. Second, as Director of DFOI, I do not have authority to order FDA staff from other program offices – many of whom are actively involved in the agency's extensive efforts to respond to the COVID-19 pandemic – to support the agency's disclosure functions. Further, even if the agency did suddenly allocate significant new monetary resources to hire new disclosure staff, it would take substantial time to recruit and hire new staff, bring them on board, and provide them with the necessary training to become competent to perform disclosure reviews. FDA estimates that it takes approximately two years to fully train a new disclosure reviewer. In the meantime, experienced reviewers would be needed to supervise and review their work – thus decreasing the amount of time that experienced reviewers can spend reviewing records.

Kotler Decl. ¶ 22 (App120-21).

In short, while FDA takes its FOIA obligations seriously, and is fully committed to the important values of transparency and openness embodied by that statute, its primary mission is to protect and improve public health and safety. *See* 21 U.S.C. § 393 (establishing "Mission" of FDA). Even if it were theoretically possible for FDA to re-assign its scientists and other programmatic staff to process Plaintiffs' FOIA request—which it is not—any such reallocation of personnel would come at an unacceptable cost to public health and safety, particularly at a time when the country continues to grapple with a yet ongoing, once-in-a-century global

pandemic. The unprecedented measures sought by Plaintiff are nowhere contemplated or authorized by FOIA, and this Court should reject them in no uncertain terms.

C. Plaintiff's Proposal Is Contrary to the Public Interest

Additionally, ordering Defendant to disclose documents, not "as soon as practicable" as dictated by FOIA, 5 U.S.C. § 552(a)(6)(E)(iii), but rather on Plaintiff's preferred (and wholly infeasible) timetable is contrary to the public interest, in at least two respects.

First, Plaintiff's proposal fails to account for, or pay even passing lip service to, the public interest of the many hundreds of other parties with FOIA requests pending before FDA's Center for Biologics Evaluation and Research ("CBER"), whose request would be delayed. Although those requestors are not before the Court in this action, they presumably have interests in receiving the documents that they sought in order to further the important interests that motivated them to submit FOIA requests. Plaintiff has offered no explanation as to why its request is more beneficial than the hundreds of other COVID-19-related requests that Plaintiff seeks to leapfrog. Ordering FDA to complete Plaintiff's request on an artificial timeline would require that resources be diverted from other requests, thus harming other requestors' interests as well as the overall public interest in the proper administration of FOIA, including its provision for expedition. *See, e.g.*, *New York Times Co.*, 2021 WL 1614817, at *4 (denying plaintiff's request to enter a preliminary injunction ordering the agency to produce responsive records on an expedited basis and by a date certain, on the grounds that, *inter alia* "the likely massive volume of responsive data … [and] the concomitant heavy processing burden on defendants" would "result[] [in] disruption of the ordinary FOIA processing on similarly-situated FOIA requesters"); *id.* at *10 (emphasizing the interests of "similarly situated FOIA requesters, who are depending on, and adhering to, regular administrative FOIA record production processes to

obtain information important to them … Hundreds of individuals and organizations await the results of pending requests, filed ahead of plaintiff's requests, and also seek information relating to the COVID-19 pandemic … Plaintiff's assurance that this is not a case of trying to 'leap frog' to the front of the line … rings hollow under these circumstances."); *Protect Democracy Project Inc. v. U.S. Dep't of Def.*, 263 F. Supp.3d 293, 303 (D.C.C. 2017) ("[R]equiring production by a date certain, without any factual basis for doing so, might actually disrupt FOIA's expedited processing regime rather than implement it.").

Second, granting Plaintiff's request for an infeasible and extraordinary processing schedule would compromise the public interest in ensuring that certain types of documents, the disclosure of which would cause harm, are carefully redacted consistent with the FOIA exemptions. The exemptions listed in § 552(b) embody a judgment that the public interest would be served best by allowing agencies to withhold certain records (or information within records). Indeed, Congress has recognized that, in certain cases, depending on the subject matter of the request, additional time would be required to ensure that the public's interest in preventing the public disclosure of these exempted documents was not compromised: "In underscoring the requirement that agencies respond to requests in a timely manner, the Committee does not intend to weaken any interests protected by the FOIA exemptions. Agencies processing some requests may need additional time to adequately review requested material to protect those exemption interests." H.R. Rep. No. 104-795.

Risk of inadvertent disclosure is an especially weighty consideration here because, in Defendant's experience, a significant portion of the records at issue are likely to contain confidential commercial and/or trade secret information protected by Exemption 4, *see, e.g., Public Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983) ("Because

documentation of the health and safety experience of their products will be instrumental in gaining marketing approval . . . , it seems clear that the manufacturers . . . have a commercial interest in" information submitted to FDA regarding clinical studies of investigational devices) or the personal or medical information of clinical trial participants, which is protected by Exemption 6. 5 U.S.C. § 552(b)(4), (6). Moreover, if FDA determines not to withhold information that might be confidential commercial information, it is sometimes required to provide notice to the company that submitted the information and an opportunity to file a claim for injunctive relief (a "reverse FOIA" claim). *See e.g.,* 21 C.F.R. 20.47, 20.48, 20.61(e).

With respect to the latter category of privacy concerns, Plaintiff asserts that "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." Pl. Br. at 25. But, despite any efforts the sponsor may have made pursuant to 21 C.F.R. § 20.63(b) to anonymize the data it submitted, FDA has an independent responsibility to ensure that any information that would identify patients or research subjects is deleted before the record is disclosed. 21 C.F.R. § 20.63(a); *see* 5 U.S.C. § 552(b)(6). And, indeed, in the productions FDA has already made, the agency has identified and redacted personal privacy information. For example, in the interim production that FDA is making today, the agency has redacted dozens of dates of birth and death, consistent with Exemption 6. Thus, the risk of inadvertent disclosure is real—and indeed, especially acute where, as here, a FOIA request implicates third party medical information, where the interest in carefully analyzing exemption questions carries particular significance.

Thus, ordering FDA to disclose documents, not "as soon as practicable" as dictated by FOIA, 5 U.S.C. § 552(a)(6)(E)(iii), but rather on any artificial, and indeed unprecedented

timetable, threatens to risk disclosure of statutorily exempt material. *See Daily Caller*, 152 F. Supp. 3d at 14 ("Requiring the agency to process and produce [requested] materials under an abbreviated deadline raises a significant risk of inadvertent disclosure of records properly subject to exemption under FOIA."); *Protect Democracy Project*, 263 F. Supp. 3d at 302 ("Imposing on Defendants an arbitrary deadline for processing would run the risk of overburdening them, and could even lead to the mistaken release of protected information."); *Baker*, 2018 WL 5723146, at *5 ("Ordering Defendant to process and release documents according to Plaintiff's timeline risks that, in its haste, Defendant will inadvertently release records which fall under a FOIA exception and Congress has decided should not be released."). Plaintiff's demand that FDA process records responsive to its Request essentially overnight fails to recognize, much less account for, this important concern.

D. Plaintiff Chose to File an Exceedingly Broad Request and Has Declined to Narrow It

In similar situations, courts presented with broad and burdensome FOIA requests and a concomitant dearth in agency resources look to the requester's efforts at narrowing the request in assessing a reasonable processing rate. *See, e.g., Nat'l Day Laborer Org. Network*, 236 F. Supp. 3d at 819 ("The Court is particularly mindful" "of the strain that defendant's FOIA responsibilities may pose," "given the significant breadth of plaintiffs' request and plaintiffs' failure to effectively narrow their request at the administrative stage and during this litigation."). Plaintiff can control the scope of its FOIA request, and, to date, has refused to narrow it even slightly. In its opening memorandum, Defendant described in detail its efforts to provide Plaintiff with useful, high-level information that it could use to make informed decisions as to (1) how to narrow the scope of its request to a more manageable universe of documents; and/or (2) a priority list—that FDA will make is best efforts to honor—of the records that Plaintiff is most

interested in, and thus would like to receive soonest. *See* Def. Br. at 4-5. But although Plaintiff provided Defendant with an initial priority list—which, as explained, Defendant is honoring in both its initial processing efforts and its proposed schedule for future processing, *see id.* at 5-9—Plaintiff has, to date, declined to narrow the scope of its request. Defendant reiterates that it remains committed to working collaboratively with Plaintiff to identify additional documents for prioritization, so that Plaintiff will receive the information it is most interested in, soonest. But if Plaintiff continues to decline to narrow its request, it cannot have it both ways—*i.e.*, simultaneously demand in excess of 300,000 pages of records *and* expect this volume of records to be produced overnight. Thus, to the extent that Plaintiff is dissatisfied with the amount of time it will take FDA to process in excess of 300,000 pages, it possesses the unilateral wherewithal to narrow its request to a more manageable set of records. Conversely, if Plaintiff continues to decline to narrow, that is its right under FOIA—but in that case, Plaintiff must accept the trade-off that this work will take time.

E. FDA's Proposal Effectively Accelerates Plaintiff's Request to the Extent Feasible, and Will Not Take 55 Years to Complete

As set forth in detail in FDA's opening memorandum, *see* Def. Mem. at 4-6, FDA invited Plaintiff to provide it with a Priority List of the categories of responsive records as to which Plaintiff has the strongest interest. And upon obtaining this list, FDA has endeavored to process the categories of records prioritized by Plaintiff for its earliest productions. Moreover, taking into account FDA's interim production that is scheduled to be made later on the same day as the instant filing, FDA has, to date, already produced over 3,000 pages to Plaintiff—a count that, under FDA's proposal, would very rapidly rise to more than *12,000 pages,* plus 11 unpaginated .txt or SAS data files by the end of January. Thus, Plaintiff's hyperbolic assertion that FDA is proposing an approximate 55 year response period is simply not correct—and is, indeed, directly

belied by FDA's indication that it will produce in excess of 12,000 pages in very short order.

As FDA has explained, it has not yet had an opportunity to fully assess the amount of time it will take to process other records responsive to Plaintiff's FOIA request, following its proposed January 31, 2022 production. Accordingly, from the position in which it now sits, FDA proposes to make one production at the end of each subsequent month totaling a *minimum* of 500 pages.[8] Moreover, as FDA has repeatedly explained, this proposed minimum is a floor, not a ceiling; thus, and if FDA is able to process records at a faster pace, its proposal commits it to do so—as, indeed, is reflected by the good faith, accelerated efforts the agency has already made and committed to continue to make, resulting in the production of in excess of 12,000 pages in a matter of mere months.

Moreover, as FDA has emphasized, its proposed rate of a minimum of 500 pages per month is based, in substantial part, on certain limitations that inhere, at this early stage, in the agency's ability to assess the full corpus of responsive records. FDA expects to be in a better position to make a more refined and accurate assessment regarding the feasibility of a more streamlined processing schedule by the time it makes the January 31, 2022 production. But—for all of the reasons Defendant has explained—FDA simply cannot, at this juncture, commit to a schedule of more than 500 pages per month without harming the public interest in the orderly,

[8] As Defendant has explained in prior filings, 500 pages per month is consistent with processing schedules entered by courts around the country--even where that schedule will result in lengthy production periods . *See* Def. Br. at 13; Dkt. No. 18 at 8 n.5; Dkt. No. 20 at 4 n.3; *see also White v. Exec. Off. Of U.S. Atty's*, 444 F. Supp. 3d 930, 965 (S.D. Ill. 2020) (approving 500 pages per month and nine-year production period); *Colbert v. FBI*, No.16-cv-1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (approving 500 pages per month and a decade-long production period); *cf. Nat'l Sec. Counselors v. U.S. Dep't of Justice*, 848 F.3d 467, 471-72 (D.C. Cir. 2017) (in context of challenge to FOIA processing fees, stating policy of processing 500 pages per request per month "serves to promote efficient responses to a larger number of requesters").

fair, and efficient administration of FOIA.

Accordingly, to the extent that the Court declines to adopt FDA's proposal in full, the agency respectfully requests that the Court partially adopt its proposal now—*i.e.*, approve FDA's proposal for the production of more than 12,000 pages by January 31, 2022—and then revisit the issue of a longer-term processing and production schedule with both parties in February 2022. That approach would afford Plaintiff time to assess how it might productively narrow its request; afford FDA more time to assess whether faster processing may be possible for at least certain subsets of the responsive records; and also afford both parties more time to use their best efforts to negotiate a mutually agreeable processing schedule. In the meantime, the partial adoption of FDA's proposal will ensure that the agency maintains a full-court press ahead, while adequately protecting the important public interests discussing in Defendant's opening brief, and above.

III. If Plaintiff Expands the Meaning of its FOIA Request, Substantial Additional Processing Time Will Be Necessary

Finally, Plaintiff in its reply brief takes issue with Defendant's understanding of the FOIA request at issue. Defendant believes that its interpretation of the request is reasonable. However, in the event Plaintiff insists on an expanded interpretation of its request, it faces unavoidable trade-offs in this choice: a broader construction of Plaintiffs request would capture tens of thousands of additional documents beyond the universe of approximately 329,000 pages (and at least 126 .txt and/or SAS data files) identified to date, and thus add substantial additional time for completion of processing.

Plaintiff's FOIA request sought "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." Burk Decl. ¶ 24 (App011). Because the regulation cited by Plaintiff, 21 C.F.R. § 601.51, addresses "data and information in applications for

biologics licenses," FDA interpreted Plaintiff's FOIA request as a request for all publicly releasable information in the original biologics license application ("BLA") submitted by BioNTech-Pfizerfor the Comirnaty vaccine with internal file number STN 125742/0/0. Burk Decl. ¶ 25 (App011–12). However, as defense counsel explained to Plaintiff's counsel in the course of the parties' conferral efforts: the Cominarty biological product file, of which the BLA is a subset:

> also contains supplements, amendments, and product correspondence. FDA estimates that there are approximately 39,000 pages of records in that category. In addition, there may be investigational new drug records [("IND")] that may be supportive of the BLA. Although we cannot provide a precise count, FDA estimates that there would be tens of thousands of additional pages in this category. These page counts are in addition to FDA's estimate of 329,000+ pages (plus data files) in the original Cominarty BLA.

Ex. E (Dec. 2, 2021 email from Courtney Enlow to Aaron Siri) (App140-41).

After Plaintiff's counsel inquired further about these additional pages, defense counsel further elaborated that:

> FDA knows that there are a number of records in the IND section of the biological product file; however, it would take a closer review of those pages to determine which information would be considered supportive of the BLA/licensure and, thus, publicly available (subject to disclosure review) under 21 C.F.R. 601.51(e).
>
> You may already be aware of this, but to make sure we're on the same page – IND files may include studies for several forms (different dose strengths, formulations, etc.) and/or indications (different disease conditions, age groups, etc.). It's possible for a biological product to be approved for only a subset of the variations/indications for which it was originally studied. The portions of the IND file related to the approved conditions would become part of the biological product file that would be available for disclosure (subject to confidentiality review) once the product is approved; portions of the IND related to unapproved forms/indications would remain confidential (as would the existence of these portions).
>
> To be clear, FDA disclosure staff have not yet determined whether portions of the IND section of the Comirnaty file refer to forms or conditions that are have not been approved under a BLA. Thus, this response should not be understood as an indication that any parts of the biological product file relate to INDs associated

> with a product that has not been approved. But, before performing that review (which would require a substantial investment of time from FDA), we cannot provide a precise page estimate. Because, again, the FDA assesses that that this effort does not justify the diversion of resources away from its processing work, it also cannot accommodate this request at this time.

Ex. F (Dec. 10, 2021 email from Antonia Konkoly to Aaron Siri) (App145-46).

While FDA believes that its original (and extant) construction of Plaintiff's request is both proper and reasonable, to the extent that Plaintiff wishes to additionally obtain one or both of the above-described additional categories of documents, FDA can expand its interpretation of the request. That choice is Plaintiff's to make, but Plaintiff must acknowledge and accept the unavoidable consequence that tens of thousands of documents simply cannot be added to the FDA's processing queue without moving the goal post of the processing completion date significantly further into the future.

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court enter FDA's proposed processing schedule.

Dated: December 13, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2021, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

/s/ Antonia Konkoly

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EXHIBIT D

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

DECLARATION OF SARAH B. KOTLER

I, Sarah B. Kotler, declare as follows:

1. I am the Director of the Division of Freedom of Information (DFOI), Office of the Executive Secretariat, Office of the Commissioner, Food and Drug Administration (FDA), United States Department of Health and Human Services (HHS), in Rockville, Maryland.

2. I have held the position of Director of DFOI since January 2015. Prior to becoming Director, I served as Acting Director of DFOI from November through December 2014, after the former Director of DFOI retired. I previously served as DFOI's Deputy Director and Denial & Appeals Officer from September 2013 through October 2014; and as Denials & Appeals Officer from March 2007 through August 2013.

3. As both Deputy Director and Director, I have had supervisory authority over DFOI, which serves as FDA's official point of receipt for all requests for records under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. *See* 21 C.F.R. § 20.40. In addition, DFOI is responsible for FDA's FOIA reporting to HHS and the U.S. Department of Justice, consulting with other federal agencies regarding FOIA requests, agency-wide FOIA training, and expedited

processing, among other functions. DFOI processes about 25% of all FOIA requests received by FDA; the other 75% are processed by the FOIA reviewers within FDA's other components.

4. As part of my duties, I have been coordinating FDA's processing of FOIA requests that relate to the novel coronavirus known as SARS-CoV-2, also known by the disease it causes, COVID-19. Due to the nature of my official duties, I am familiar with the procedures followed by FDA in responding to requests for information from its files pursuant to provisions of the FOIA, 5 U.S.C. § 552, among others. I am aware of the workload obligations of the various offices that process FOIA requests across the agency.

5. The statements contained in this declaration are based upon my personal knowledge, upon information provided to be in my official capacity, and upon conclusions I reached based on that knowledge or information.

6. The purpose of this declaration is to provide an overview of FDA's procedure for handling FOIA requests and its capabilities in processing Plaintiff's FOIA request in particular. This declaration also documents the agency's basis for denying Plaintiff's request for expedited processing.

7. As explained below, Plaintiff's Request did not satisfy the standard for expedited processing because it did not establish an urgent need to inform the public about federal government activities. Further, Plaintiff's suggestion that FDA should be able to reallocate resources to respond to Plaintiff's FOIA request is not feasible and could violate FDA's obligations with respect to other FOIA requesters. Since the beginning of the COVID-19 pandemic, FDA has experienced a sudden surge of incoming FOIA requests, an increase in the complexity of those requests, and an uptick in the amount of FOIA litigation it faces. These factors, when combined with the Agency's existing FOIA and non-FOIA workload, prevent

other FDA components from being available to assist the Center for Biologics Evaluation and Research ("CBER") to process Plaintiff's Request without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiff's, as well as other non-FOIA record requests. Such diversion would adversely impact the Agency's ability to meet stipulated document processing deadlines and prejudice other pending requests.

FDA'S GENERAL PROCEDURE FOR INCOMING FOIA REQUESTS

8. Under FDA's regulations, DFOI is the office responsible for FDA's compliance with FOIA. *See* 21 C.F.R. §§ 20.30, 20.40. When DFOI receives an electronic FOIA request, it generates a control number that begins with four digits reflecting the calendar year in which the request was received, followed by the number of FOIA requests received by DFOI to date in that particular calendar year. For example, Plaintiff's request has the control number "2021-5683" because it is the 5,683rd FOIA request received by FDA in calendar year 2021.

9. FDA provides expedited processing of a request for records when the requester demonstrates a compelling need and in other cases determined by the agency. *See* 5 U.S.C. § 552(a)(6)(E). A compelling need exists when: (1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or (2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity. *Id*. DFOI reviews requests for expedited processing and sends a letter to the requester documenting FDA's determination as to whether expedited processing has been granted or denied. In accordance with 21 C.F.R. § 20.44, requests that have

been granted expedited processing are processed as soon as practicable, on a first-in, first-out basis based on the date of receipt.

10. Because of FDA's size and the large number of records generated during the course of agency business, and the different components within FDA, the agency's FOIA program is decentralized. After a FOIA request is received and logged by DFOI, the request is assigned to the FDA components reasonably likely to possess responsive records, which then process the request. FOIA reviewers within each assigned component process potentially responsive records and determine whether they should be released in full, redacted in part, or withheld in their entirety under any applicable FOIA exemption or other statutory or regulatory provision.

FDA'S PUBLICATION OF INFORMATION RELATED TO COMIRNATY VACCINE

11. In an effort to inform the public about its work related to COVID-19, FDA has made an abundance of information available on its website – both about the Comirnaty vaccine specifically and the agency's COVID-19 response generally. The homepage of FDA's website prominently features a link to information about the "FDA COVID-19 Response." FDA, https://www.fda.gov/. Clicking on that link takes the user to a page with numerous links to additional information about FDA's response. The linked webpages provide information about COVID-19 vaccines, emergency use authorizations, personal protective equipment, FDA guidance documents, Frequently Asked Questions, and resources for health professionals, among many other things. FDA, Coronavirus Disease 2019 (COVID-19), https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19.

12. From that page, the user can access the "Comirnaty and Pfizer-BioNTech COVID-19 Vaccine" page. FDA, Comirnaty and Pfizer-BioNTech COVID-19 Vaccine,

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty (printout attached as Exhibit A to this declaration). That page contains links to a host of important information about the Comirnaty vaccine, including Frequently Asked Questions for Comirnaty, information sheets for healthcare providers, regulatory information, media materials and webcasts, advisory committee information, and even links to video recordings of virtual meetings of FDA's advisory committee (the Vaccines and Related Biological Products Advisory Committee). *Id.* The webpage even includes translations of certain information in multiple languages, including Spanish, Chinese, Korean, Russian, among many others. *Id.*

13. Clicking on the "Comirnaty Information" link on that page brings the user to yet another page with more information specific to the Comirnaty vaccine. FDA, Comirnaty, https://www.fda.gov/vaccines-blood-biologics/comirnaty. This page contains the "Action Package" for Comirnaty, required by the Food and Drug Administration Amendments Act of 2007 to be posted within 30 days of approval. The agency expects the Action Package to be of interest and most useful to the public in understanding its approval decision. It provides access to the package insert, the Summary Basis for Regulatory Action, the Approval Letter, FDA decision memoranda, and approval history. Many of these records were posted shortly after the Comirnaty biological license application ("BLA") was approved on August 23, 2021. For example, FDA posted its "Summary Basis for Regulatory Action" the day after the Comirnaty BLA was approved; it posted the Action Package, including FDA discipline review memos such as clinical, statistical and toxicology reviews, approval letter, and package insert, within 25 days of approval. FDA's Comirnaty page currently contains links to approximately 700 pages of Action Package records related to the Comirnaty vaccine licensure. *Id.* These records often contain summaries of

the information and data submitted by Pfizer and BioNTech that FDA reviewed and assessed, as well as FDA's assessment, that support FDA's decision to license the Comirnaty vaccine. As just one example of the types of information available, there is a 107-page August 23, 2021, "BLA Clinical Review Memorandum." That memorandum includes sections entitled, "Clinical and Regulatory Background," "Submission Quality and Good Clinical Practices," Significant Efficacy/Safety Issues Related to Other Review Disciplines," Discussion of Individual Studies/Clinical Trials," and the FDA reviewers' conclusions and recommendations based on the data reviewed. *See id.* (under link to "Approval History, Letters, Reviews, and Related Documents – COMIRNATY").

14. FDA continues to regularly update these websites to provide the most current and relevant information about COVID-19 to the public as soon as possible.

FDA'S PROCESSING OF PLAINTIFF'S REQUEST

15. On August 27, 2021, Plaintiff submitted to FDA a request ("Plaintiff's Request") seeking, "[a]ll 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." Plaintiff's Complaint, ECF No. 1-1, Ex. A.1 at 1. FDA assigned Plaintiff's Request the control number 2021-5683. Plaintiff's Request is extremely broad, calling for the agency to review the entire BLA for the Pfizer-BioNTech Comirnaty COVID-19 vaccine to determine which information is available for release to the public under 21 C.F.R. § 601.51(e).

16. I assigned Plaintiff's Request to CBER for processing because it sought information – a BLA – in CBER's custody. CBER's processing of Plaintiff's Request is described in more detail in the December 6, 2021, Declaration of Suzanne Burk ("Burk Decl."), ECF No. 23 at Ex. A. As described in that declaration, CBER expended great efforts to negotiate the scope of

Plaintiff's request—and in particular, to supply Plaintiff with information it could use to narrow its Request to a more manageable universe of documents, which the FDA could, correspondingly, process more quickly—as well as a production schedule for Plaintiff's Request. However, to date, the parties have not been able to agree to either any modification of the scope of Plaintiff's request, or to a production schedule. *See* Burk Decl. ¶¶ 26-27.

REQUEST FOR EXPEDITED PROCESSING

17. Plaintiff's Request included a request for expedited processing. I carefully reviewed that request for expedited processing, and I determined that Plaintiff did not demonstrate a compelling need under 5 U.S.C. § 552(a)(6)(E), in substantial part because of the large amounts of information that have already been made available to the public about the Comirnaty vaccine and related FDA activities. A compelling need exists when: (1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or (2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity. *Id*. Department of Justice guidance advises agencies to "carefully" assess the merits of expedited processing requests "[b]ecause the granting of a request for expedition necessarily works to the direct disadvantage of other FOIA requesters." U.S. Department of Justice, FOIA Update: OIP Guidance: When to Expedite FOIA Requests, https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

18. Plaintiff's Request did not contain any basis to conclude that a failure to obtain records on an expedited basis would pose a threat to any individual. As a result, I concluded that Plaintiff had not satisfied the first criterion for expedited processing.

19. Plaintiff's Request did assert that Plaintiff was an organization primarily engaged in disseminating information and explained why it believed it was urgent to inform the public about government activities related to the Comirnaty vaccine. Plaintiff first explained that it believed that there was an "ongoing, public national debate" about FDA's decision to license the Comirnaty vaccine, quoting numerous individuals, including a number of Plaintiff's members, with varying opinions about the vaccine. Second, Plaintiff noted that many organizations had mandated COVID-19 vaccines for their members or employees.

20. After considering Plaintiff's explanation, I determined that Plaintiff had not established that it had demonstrated urgency to inform the public concerning actual or alleged Federal Government activity, largely because there is a significant amount of information already available to Plaintiff and the public concerning FDA's activities surrounding the Comirnaty vaccine. As discussed above (*see*, *supra*, ¶¶ 11-14), FDA is posting a significant amount of information related to the Comirnaty vaccine on its website on an ongoing basis. The documents posted by the agency currently contain, among other things, FDA review memoranda, which include summaries of safety and effectiveness data, as well as FDA reviewers' analyses of them. FDA's sister agency, the Centers for Disease Control and Prevention ("CDC") also maintains a website with additional information about Comirnaty ingredients, summaries of safety data, and clinical trial evidence about efficacy. CDC, Pfizer-BioNTech COVID-19 Vaccine (also known as COMIRNATY) Overview and Safety, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html. CDC also provides the public with access to its WONDER database, which contains adverse event report data collected through the U.S. Vaccine Adverse Event Reporting System. CDC, How to Access VAERS Data through VAERS WONDER System, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/

vaers/access-VAERS-data.html. As a result, the public has access to a large amount of information about the vaccine and government actions related to the vaccine's review and approval.

21. The fact that people may have differing opinions about a certain FDA-regulated product does not create "urgency" within the meaning of the expedited processing standard for the agency to produce an entire BLA – especially in light of the amount of information published on FDA's website. Nor does the fact that certain individuals may be administered a certain product. FDA approves medical products regularly in the course of agency business. It is not unheard of for those approvals to be the subject of controversy, and there are almost always people who are administered the products shortly after approval. Such a situation cannot be deemed to create an urgent need for the agency to expedite its review and processing of the hundreds of thousands of pages of records, especially when the agency routinely publishes summaries of safety and efficacy information on its website (as it did here). If Plaintiff's view became the standard, a great number of FDA's FOIA requests would qualify for expedited processing, and requesters with non-expedited requests would have their wait times extended – possibly significantly. Thus, Plaintiff's claim that its request would fulfill an urgent demand is not supported, and I denied its request for expedited processing.

ALLOCATION OF AGENCY RESOURCES

22. I understand that Plaintiff has suggested that FDA should reallocate resources from other agency functions to help process Plaintiff's Request. This suggestion is not feasible, or even beneficial, for a number of reasons. First, performing disclosure reviews is a specialized skill that requires training and expertise that the vast majority of FDA staff does not have. It is not reasonable to expect that a microbiologist who performs laboratory assays, a pharmacist who reviews drug applications, a badging office employee who issues credentials, or a mail room clerk

who organizes mail can simply begin performing disclosure review without significant training. Moreover, it would be contrary to FDA's public health mission to pull staff off reviewing cancer treatment applications or building counterfeit medication investigations to have them conduct work for which they are untrained and unqualified. Second, as Director of DFOI, I do not have authority to order FDA staff from other program offices – many of whom are actively involved in the agency's extensive efforts to respond to the COVID-19 pandemic – to support the agency's disclosure functions. Further, even if the agency did suddenly allocate significant new monetary resources to hire new disclosure staff, it would take substantial time to recruit and hire new staff, bring them on board, and provide them with the necessary training to become competent to perform disclosure reviews. FDA estimates that it takes approximately two years to fully train a new disclosure reviewer. In the meantime, experienced reviewers would be needed to supervise and review their work – thus decreasing the amount of time that experienced reviewers can spend reviewing records. As a result, it is not reasonable to expect that FDA will be able to respond to Plaintiff's Request more quickly by allocating non-disclosure resources to processing it. In fact, to do so would significantly impede FDA's public safety role.

23. And, as discussed in the following section, it is not feasible for the agency to reallocate its existing disclosure resources to work on Plaintiff's Request because the agency's disclosure staff is already over-extended by existing disclosure obligations.

PROCESSING WORKLOAD OF DISCLOSURE OFFICES OUTSIDE OF CBER

24. As an initial matter, the disclosure office of each FDA component has its own specialized responsibilities and expertise. Thus, although all disclosure staff will be familiar with general principles of FOIA, staff from different centers will be trained to review information regularly generated within that center. For example, CBER reviewers are familiar with the types

of information regularly contained in BLAs and are trained to identify information that may be exempt from disclosure in those types of files; CBER reviewers would not be familiar with the types of records commonly processed by other parts of the agency, such as premarket tobacco product applications or food additive petitions. The converse is also true; reviewers in FDA's Center for Food Safety and Applied Nutrition ("CFSAN") are familiar with records regularly generated within CFSAN, but would not have the same expertise as a CBER reviewer when looking at a BLA. Thus, even disclosure staff within the agency should not be considered interchangeable.

25. Further, on March 13, 2020, the President declared a national emergency due to the ongoing COVID-19 pandemic. Since the beginning of this emergency, FDA has been flooded with FOIA requests related to the pandemic.

26. Specifically, in the last fiscal year, FDA received approximately 8,529 FOIA requests, many of which are directly related to COVID-19. Of these, an extremely high 99 requests (1.16%) have been granted expedited processing. Historically, FDA has had fewer than five expedited requests at any one time, and often fewer than five. For example, in 2019, FDA granted expedited process for only 0.017% of requests received. In short, the number of FOIA requests meriting expedited processing has grown exponentially since the beginning of the COVID-19 pandemic.

27. Further complicating matters, many of the more recent FOIA requests are more complex and are expected to take longer to process than typical FOIA requests received prior to the beginning of the COVID-19 pandemic. Many requests for information related to COVID-19 require collaboration among federal agencies because they involve records (such as emails) that may have originated in other agencies. Department of Justice guidance advises federal agencies

to consult with the originating agency for disclosure determinations. U.S. Department of Justice, FOIA Update: OIP Guidance: Referral and Consultation Procedures, https://www.justice.gov/oip/blog/foia-update-oip-guidance-referral-and-consultation-procedures. As a result, FDA regularly collaborates with other federal agencies, such as CDC, the National Institutes of Health, and the Department of Health and Human Services, about records responsive to requests. These consultations add both time and complication to the process for responding to FOIA requests.

28. Coupled with the unprecedented number of FOIA requests that merit expedited processing and the increased complexity of requests, FDA recently experienced a significant increase in FOIA litigation. Between calendar years 2017 and 2019, the number of FOIA lawsuits filed against the Agency grew by approximately 70%; between calendar years 2018 and 2020, the number of FOIA lawsuits filed against FDA grew by approximately 200%. Although the number of lawsuits so far in 2021 has decreased from 2020 levels, FDA has been the subject of 11 lawsuits in 2021, which is an increase of 83% from 2018 level. Currently, FDA is involved in approximately 34 active FOIA litigations, with nine matters involving COVID-19 records.

29. At the review and redaction phase, certain FDA components have had to shift some of their FOIA reviewers from responding to FOIA requests in the normal course to almost exclusively processing FOIA requests in litigation. This diversion of staff resources to respond to ever increasing litigation and impending court deadlines means that fewer initial FOIA requests are being processed, and at a slower pace, which is causing even more litigation.

30. In addition to FOIA, FDA also has numerous other document processing obligations, including those arising from subpoenas; non-FOIA litigations; oversight requests from Congress; requests and domestic and foreign regulatory bodies; and other statutory disclosure

mandates. In some agency offices, the same staff that handles FOIA requests also handles these other disclosure projects as they rely on similar disclosure skills. As a result, it would not be feasible for FDA to shift resources from other disclosure offices to help CBER process Plaintiff's Request. In the following paragraphs, I discuss the current workload of various FDA components.[1]

Center for Drug Evaluation and Research ("CDER")

31. As of November 30, 2021, CDER is responsible for processing 855 pending FOIA requests. This is a significant increase in pending requests compared to past years, partly due to increased burden resulting from work related to COVID-19 FOIA requests and other disclosure obligations. CDER is responsible for processing at least 170 FOIA requests related to COVID-19. The following chart illustrates the increase in the length of CDER's FOIA queue as of November 30 of each calendar year.

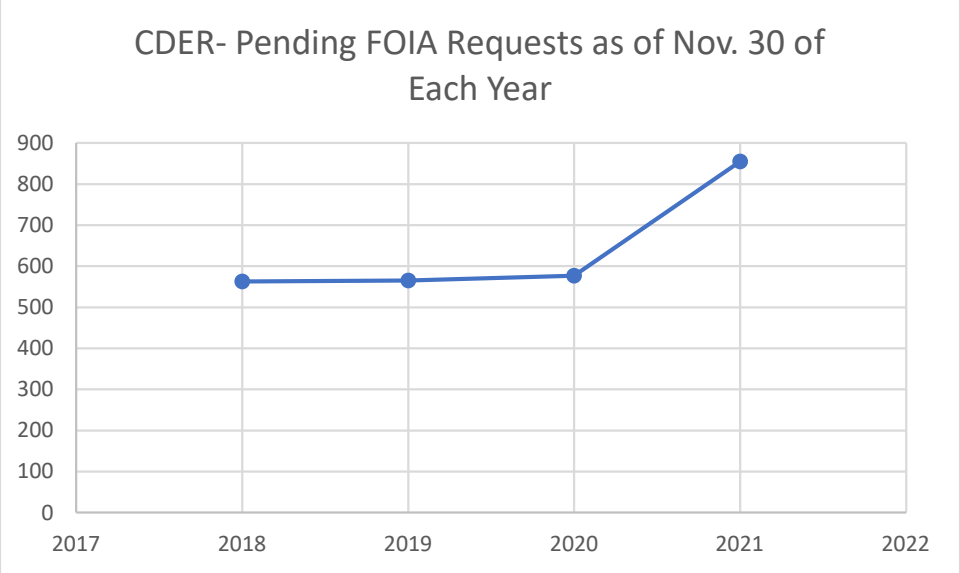

Figure 1: *Pending FOIA Requests in CDER as of November 30 of each year from 2018 to 2021.*

[1] I do not include a discussion of CBER's workload because that information was included in the December 6, 2021, Burk Declaration. ECF No. 23, Ex. A.

32. In addition to processing FOIA requests, CDER is also responsible for processing other document requests made by Congress; the U.S. Government Accountability Office; foreign, state, and local governments; and other federal agencies. Although these requests are not made under FOIA and are not processed in CDER's FOIA tracks, they are processed by CDER's FOIA reviewers because of the similar nature of the work to FOIA processing and the need for consistency in reviewing and redacting responses to information requests. Since 2019, these responses have required the attention of up to four employees. Because some of these employees were pulled from other tasks to work on these matters, there was a corresponding decrease in reviewers' time available to respond to FOIA requests. In recent years, CDER has produced tens of thousands of pages in response to requests from foreign regulatory authorities for documents regarding FDA inspections of foreign drug manufacturers, and in response to requests from the Department of Justice related to its investigations of pharmaceutical companies. CDER also has other statutory disclosure obligations under the Food and Drug Administration Amendments Act of 2007, which requires that New Molecular/Biological Entity (NM/BE) action packages be published on CDER's web page within 30 days of approval. In 2019, CDER reviewed and redacted 46 NM/BE action packages, and in 2020, CDER reviewed and redacted 20 NM/BE action packages, each of which typically contains thousands of pages.

Office of the Commissioner ("OC")

33. As of November 30, 2021, OC has 435 pending FOIA requests. At this time, OC has 1 full time employee working on FOIA requests. Since the fall of 2020, OC has brought in detailees for 90 to 120 day periods to assist the FOIA FTE. Despite my other duties, including management of my division, I have been assisting with FOIA review for COVID requests in OC, as well as keeping the non-COVID OC FOIA workload moving. OC is currently involved in 8

active litigation matters. As with CDER, this represents a significant increase in pending requests compared to past years. The following chart illustrates the increase in the length of OC's FOIA queue as of November 30 of each calendar year.

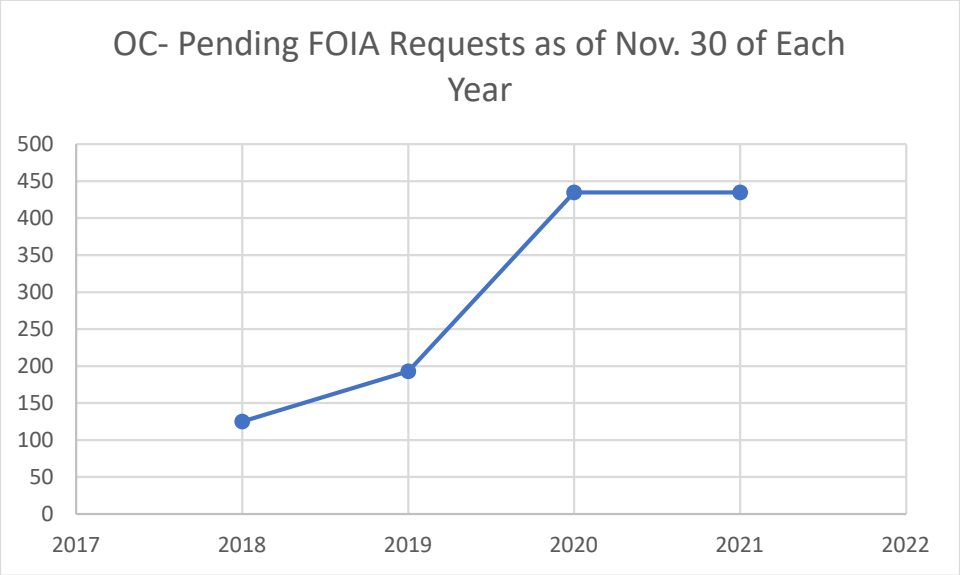

Figure 2: *Pending FOIA Requests in OC as of November 30 of each year from 2018 to 2021.*

Center for Devices and Radiological Health ("CDRH")

34. Currently, CDRH has 2,010 pending FOIA requests, approximately 124 of which are related to COVID-19. The following chart illustrates the length of CDRH's FOIA queue as of November 30 of each calendar year. Although CDRH's queue has not changed as dramatically as other FDA components, it remains the longest queue in the agency.

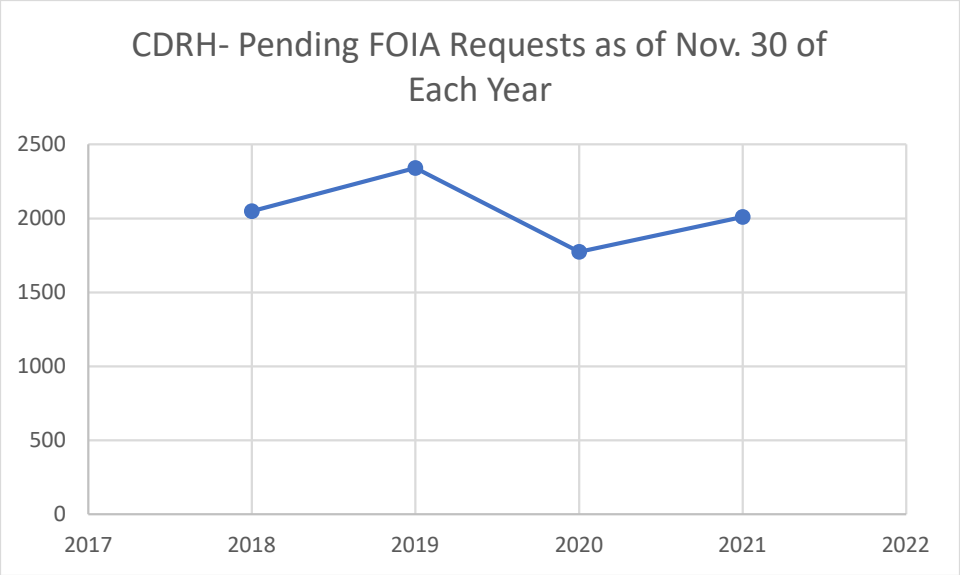

Figure 3: *Pending FOIA Requests in CDRH as of November 30 of each year from 2018 to 2021.*

35. Other than FOIA requests, CDRH's FOIA Office is also responsible for responding to subpoenas and non-FOIA record requests made by Congress; foreign, state, and local governments; and other federal agencies. Since 2015, these responses have required the attention of up to 22 employees. Because some of these employees were pulled from other tasks to work on these matters, there was a corresponding decrease in reviewers' time available to respond to FOIA requests. Within the past four years alone, CDRH produced tens of thousands of pages of documents in response to requests from other federal agencies related to their investigation of medical device companies. Furthermore, since 2018, CDRH has responded to numerous federal subpoenas, with quick turnarounds for productions that have required CDRH reviewers to stop processing FOIA requests to respond to these subpoenas. Specifically, two of the subpoenas have yielded over hundreds of thousands of pages each.

Other FDA Components

36. The components highlighted above are not outliers. Other FDA components have significant queues, some of which have grown recently as a result of increased workload related

to COVID-19. For example, the Office of Regulatory Affairs alone has devoted over 1,500 hours to responding to COVID-19 FOIA requests and has seen its number of pending requests increase from 28 in November 2018 to 91 in November 2021. Although largely unrelated to the COVID-19 pandemic, FDA's Center for Veterinary Medicine has seen its number of pending requests jump from 102 in November 2018 to 318 in November 2021, due to an increase of FOIA requests unrelated to COVID-19.

37. FDA's Center for Food Safety and Applied Nutrition and Center for Tobacco Products have not encountered the same influx of COVID-19 FOIA requests, so their FOIA queues have remained fairly steady in the 2018-2021 timeframe. But they continue to maintain queues in the 65-75 range, so their resources are fully consumed with their standard responsibilities, which also include non-FOIA disclosure projects, such as Privacy Act requests.

38. Based on all of the information above, none of FDA's other disclosure offices are able to assume the burden of taking on a significant role in the review of CBER records responsive to Plaintiff's Request without compromising their ability to keep up with their own disclosure review responsibilities, especially considering that these staff are not specifically trained to review the records at issue in this case.

EFFORTS TO REDUCE BACKLOGS

39. FDA's various FOIA offices have taken numerous steps to reduce backlogs and improve processing time. Specifically, FDA's FOIA offices are recruiting and hiring new employees where funding allows; proactively posting online frequently requested documents to reduce the need for new FOIA requests; cross-training employees in complex disclosure matters to assist with complex track requests; evaluating requests daily in order to shift them to experienced redactors as needed; and, where possible, proactively contacting FOIA requesters to

negotiate the scope of requests to in order to produce documents quickly. In particular, since August 2020, CDER has brought on six new employees to assist with FOIA processing. Similarly, CDRH completed a business process improvement review of its FOIA program in October 2019, which included identifying hiring needs; updating workflows, processes, and procedures; training reviewers; and additional tracking of FOIA requests. Between September and December 2019, CDRH acquired a multi-year contract that currently provides seven contractors to assist in reducing FOIA backlogs and hired additional full-time reviewers to process FOIA requests and other disclosure tasks. Unfortunately, this review was conducted before the onslaught of COVID-related FOIA requests were submitted, and therefore the process changes have not achieved results as quickly as expected.

CONCLUSION

40. In sum, FDA is committed to transparency in all aspects of its work, especially its response to the COVID-19 pandemic. The agency has taken proactive steps to provide an abundant amount of information to the public about the Comirnaty vaccine as soon as possible. That information is available on FDA's website, which is being updated regularly. FDA has also taken reasonable steps to respond to Plaintiff's Request, as discussed in greater detail in the Burk Declaration. But Plaintiff's Request does not satisfy the statutory standard for granting expedited processing. Further, given the limited number of FDA staff available to perform disclosure reviews and the heavy workload FDA's disclosure offices are facing, it would be unduly burdensome for FDA to reallocate resources from agency components other than CBER to process Plaintiff's Request. If required to do so, FDA's ability to perform its other agency functions, including responding to other document requests, could be impaired.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on December 13, 2021, in Rockville, Maryland.

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2021.12.13 08:47:00 -05'00'

SARAH B. KOTLER
Director of Division of Freedom of Information
Office of the Executive Secretariat
Food and Drug Administration
U.S. Department of Health and Human Services

KOTLER DECLARTION
EXHIBIT A

Comirnaty and Pfizer-BioNTech COVID-19 Vaccine

November 19, 2021: **FDA expands eligibility for COVID-19 vaccine boosters to vaccine recipients 18 and older** after completion of primary vaccination. Read more... (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters)

October 29, 2021: **FDA expands emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine** to **include children 5 through 11 years of age.** Read the press release (/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age) and watch the press conference (https://youtu.be/WLbGnS-kqTY) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Comirnaty Information

Pfizer-BioNTech Fact Sheets

Pfizer-BioNTech Fact Sheet Translations

Información sobre las vacunas para el COVID-19 (https://www.fda.gov/about-fda/fda-en-espanol/informacion-sobre-las-vacunas-para-el-covid-19)

On August 23, 2021, FDA announced the first approval of a COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 in individuals 16 years of age and older.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use and is available under the EUA as a two-dose primary series in individuals 5 years of age and older, as a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose in people 18 years of age and older.

The Pfizer-BioNTech COVID-19 Vaccine is also authorized for use as a heterologous (or “mix and match”) booster dose following completion of primary vaccination with a different available COVID-19 vaccine. For example, Moderna and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine.

On November 17, 2021, CDC, in consultation with FDA, issued emergency use instructions (https://www.cdc.gov/vaccines/covid-19/eui/index.html) to provide information about the use of the vaccine as an additional primary series dose or as a booster dose in certain individuals (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us) who completed vaccination with certain non-FDA-authorized or -approved COVID-19 vaccines.

Comirnaty (/vaccines-blood-biologics/comirnaty) Information

Information	Last Updated
Package Insert (/media/151707/download)	August 23, 2021
Summary Basis for Regulatory Action (https://www.fda.gov/media/151733/download)	November 8, 2021

Information	Last Updated
Approval Letter (https://www.fda.gov/media/151710/download)	August 23, 2021
FAQ for Comirnaty (COVID-19 Vaccine mRNA) (/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna) (Español (/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contra-el-covid-19))	October 20, 2021
CDC-issued Emergency Use Instructions (https://www.cdc.gov/vaccines/covid-19/eui/index.html)	November 17, 2021

Pfizer-BioNTech Fact Sheets (English) and FAQs

Fact Sheet / FAQs	Vaccine Recipient Group	Last Updated
For Healthcare Providers (/media/153713/download)	12 years of age and older, purple cap (must dilute)	November 19, 2021
For Healthcare Providers (/media/153715/download)	12 years of age and older, gray cap (no dilution) *This formulation is not yet available in the United States.*	November 19, 2021
For Healthcare Providers (/media/153714/download)	5 - 11 years of age, orange cap (must dilute)	October 29, 2021
For Recipients and Caregivers (/media/153716/download)	12 years of age and older	November 19, 2021
For Recipients and Caregivers (/media/153717/download)	5 - 11 years of age	October 29, 2021
Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions)	All	November 4, 2021

Pfizer-BioNTech Regulatory Information

Information	Date
Decision Memorandum Addendum (/media/154358/download)	November 19, 2021
Decision Memorandum (/media/154357/download)	November 19, 2021
Letter of Authorization (Reissued) (/media/150386/download)	November 19, 2021
Decision Memorandum (/media/153947/download)	October 29, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement)	October 26, 2021
Decision Memorandum (/media/153482/download)	October 20, 2021
Decision Memorandum (/media/152432/download)	September 24, 2021
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement)	September 17, 2021

Information	Date
Concurrence Letter (/media/151731/download)	August 22, 2021
Decision Memorandum (https://www.fda.gov/media/151613/download)	August 12, 2021
Letter Granting EUA Amendment (https://www.fda.gov/media/148877/download)	May 19, 2021
FDA Decision Memorandum (/media/148542/download)	May 10, 2021
Letter Granting EUA Amendment (/media/147390/download)	April 6, 2021
Letter Granting EUA Amendment (/media/145493/download)	January 22, 2021
Letter Granting EUA Amendment (/media/144955/download)	January 6, 2021
FDA Decision Memorandum (/media/144416/download)	December 11, 2020
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)	December 10, 2020

Media Materials and Webcasts

Information	Date
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters)	November 19, 2021
Press Release (/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age)	October 29, 2021
Press Conference (https://youtu.be/WLbGnS-kqTY) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 29, 2021
Advisory Committee Webcast (https://youtu.be/laaL0_xKmmA) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 26, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines)	October 20, 2021
Media Call (https://youtu.be/rou7tf4vaUU) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	October 20, 2021
Press Release (/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations)	September 22, 2021
Advisory Committee Webcast (https://youtu.be/WFph7-6t34M) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	September 17, 2021
Press Release (/news-events/press-announcements/fda-approves-first-covid-19-vaccine)	August 23, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised)	August 12, 2021
FDA In Brief (/news-events/press-announcements/fda-brief-fda-authorizes-longer-time-refrigerator-storage-thawed-pfizer-biontech-covid-19-vaccine)	May 19, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use)	May 10, 2021

Information	Date
Press Conference (https://youtu.be/npjhwpConSw) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	May 10, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer)	February 25, 2021
Press Release (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)	December 11, 2020
Press Conference (https://youtu.be/L0K3RsIZIP0) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	December 11, 2020
Advisory Committee Webcast (https://youtu.be/owveMJBTc2I) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)	December 10, 2020

Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers

Fact Sheet	Vaccine Recipient Group	Language
HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 5 A 11 AÑOS (/media/153829/download) (October 29, 2021)	5 - 11 years of age	Español (Spanish)
HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE COMIRNATY (VACUNA DE ARNm CONTRA EL COVID-19) Y LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 12 AÑOS O MÁS (/media/144625/download) (October 29, 2021)	12 years of age and older (/media/144615/download)	Español (Spanish) (/media/144615/download)
为接种者和护理者提供的关于用于预防2019新冠肺炎（COVID-19）的辉瑞生物技术公司2019新冠肺炎疫苗以个人使用的信息概况说明书 5岁至11岁 (/media/154061/download) (October 29, 2021)	5 - 11 years of age	中文 (Chinese, Simplified)
关于复必泰 (2019核糖核酸新冠肺炎疫苗)以及辉瑞-BioNTech2019新冠肺炎疫苗预防2019新冠肺炎的接受者和护理者须知 (/media/144615/download) (October 29, 2021)	12 years of age and older	中文 (Chinese, Simplified)
برگه حاوی اطلاعات ومعلومات برای متقاضیان و مسؤلین بهداشتی در مورد تطبیق واکسین کووید 19 مرض شیوع یافتهء سال 2019 در میان افرادیکه در سنین PFIZER-BIONTECH 5. الی 11 سال قرار دارند (/media/153840/download) (October 29, 2021)	5 - 11 years of age	دری (Dari)
صفحه معلومات واکسین برای دریافت کننده گان و مراقبت کننده گان در مورد کومیرنتی (واکسین کووید -۱۹، ام ار ان ای) و واکسین کووید-۱۹فایزر-بیو ان تک برای جلوگیری از مرض ویروس کرونا ۲۰۱۹(کووید-۱۹) (/media/153840/download) (October 29, 2021)	12 years of age and older	دری (Dari)

Fact Sheet	Vaccine Recipient Group	Language
FYÈ ENFÒMASYON SOU VAKSEN POU RECIPÈ AK MOUN K'AP PRAN SWEN SANTE SOU VAKSEN PFIZER-BIONTECH COVID-19 POU ANPECHE MALADI CORONAVIRUS 2019 (COVID-19) POU ITILIZE NAN MOUN KI GEN 5 AN RIVE 11 AN DE LAJ (/media/154063/download) (October 29, 2021)	5 - 11 years of age	Kreyòl Ayisyen (Haitian Creole)
FYÈ ENFÒMASYON SOU VAKSEN POU RECIPÈ AK MOUN K'AP PRAN SWEN SANTE SOU COMIRNATY (VAKSEN POU COVID-19, mRNA) AK VAKSEN PFIZER-BIONTECH COVID-19 POU ANPECHE MALADI CORONAVIRUS 2019 (COVID-19) (/media/144618/download) (October 29, 2021)	12 years of age and older	Kreyòl Ayisyen (Haitian Creole)
DAIM NTAWV QHIA TSEEB TXOG TSHUAJ TIV THAIV KAB MOB RAU COV NEEG TAU TXAIS KEV PAB THIAB COV NEEG ZOV TU TXOG QHOV TSHUAJ TIV THAIV KAB MOB COVID-19 PFIZER-BIONTECH LOS TIV THAIV TUS KAB MOB CORONAVIRUS 2019 (COVID-19) NTAWM COV TIB NEEGHNUB NYOOG 5 TXOG 11 XYOOS (/media/154064/download) (October 29, 2021)	5 - 11 years of age	Hmoob (Hmong)
DAIM NTAWV QHIA TSEEB RAU COV NEEG TAU TXAIS KEV PAB THIAB COV NEEG ZOV TU TXOG COMIRNATY (TSHUAJ TIV THAIV KAB MOB COVID-19, mRNA) THIAB QHOV TSHUAJ TIV THAIV KAB MOB COVID-19 PFIZER-BIONTECH LOS TIV THAIV TUS KAB MOB CORONAVIRUS 2019 (COVID-19) (/media/144653/download) (October 29, 2021)	12 years of age and older	Hmoob (Hmong)
បញ្ជីហេតុការណ៍ព័ត៌មានវ៉ាក់សាំងសម្រមាប់អ្នកទទួល និងអ្នកថែរទាំអ្ ា ំពីវ៉ាក់សាំងេវីេសី បយូទិចកូវីដ19 (PFIZER-BIONTECH COVID-19)ហដើម្បីបង្ការជម្ងឺកូវីដ-19(COVID-19) សម្រមាប់ហម្របើម្រាស់ជាមួយបុគ្គលថដលមានអាយុចាប់ពី 5 ដល់11 ឆ្នាំ (/media/154065/download) (October 29, 2021)	5 - 11 years of age	ភាសាអង់គ្លេស (Khmer)
╝ŢĿŐńĦ⌡ΛϸᅀՈώ╫Γ⌡ó► ╘□oÝψĠθ·ė♣►╝ψĴ╙ý┴┴P♫╘΄·Ĵ╙Ýí╘♠‖θ ĴΘ╫Ό□oÝψĠθ· COMIRNATY (COVID-19 VACCINE, mRNA) ╘΄·Ħ%ZĦĜZ ╝○O┴΄ĎÝΞ″Yź19 (PFIZER-BIONTECH COVID-19) ήźX■╞Ό╝ Aý♠ľ■ĂZÝΞ″Yź-19(COVID-19) (/media/144760/download) (October 29, 2021)	12 years of age and older	ភាសាអង់គ្លេស (Khmer)
5 세에서 11 세에 해당하는사람들에게 코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자와 의료진을 위한 백신 정보지 (/media/154076/download) (October 29, 2021)	5 - 11 years of age	한국어 (Korean)
코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한 코멀나티 (코비드-19 백신, 메신저 RNA)와 화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자와 의료진을 위한 백신 정보지 (/media/144620/download) (October 29, 2021)	12 years of age and older	한국어 (Korean)

Fact Sheet	Vaccine Recipient Group	Language
او تروکلن ۵ه ل ي اوکنووک هنملراي او يکنووتن اخيسي سکد وا هن په اړي سکوا د هرايل پوينخ) م۱۹د-يووک(وغيړان -PFIZER (PFIZER-BIONTECH COVID-19) سروي و۱۹ويډ-وک کال د۲۰۱۹ي د ک وناسک پروب ونکل ۱۱ نهاب تقيي حقن اموي معلنو نران د کي سک وا۱۹ويډ-وکBI (/media/154106/download)	5 - 11 years of age	Pashto
(October 20, 2021)		
FICHA INFORMATIVA PARA DESTINATÁRIOS CUIDADORES SOBRE A VACINA PFIZER-BIONTECH COVID-19 PARA PREVENIR A DOENÇA DO CORONAVÍRUS 2019 (COVID-19) PARA USO EM INDIVÍDUOS DE 5 A 11 ANOS DE IDADE (/media/154056/download)	5 - 11 years of age	Português (Portuguese)
(October 29, 2021)		
FICHA INFORMATIVA PARA DESTINATÁRIOS E CUIDADORES SOBRE COMIRNATY (COVID-19 VACINA, mRNA) E VACINA PFIZER-BIONTECH COVID-19 PARA PREVENIR A DOENÇA DO CORONAVÍRUS 2019 (COVID-19) (/media/144623/download)	12 years of age and older	Português (Portuguese)
(October 29, 2021)		
ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ О ВАКЦИНЕ PFIZER-BIONTECH COVID-19 ДЛЯ ПРЕДОТВРАЩЕНИЯ ЗАБОЛЕВАНИЯ КОРОНАВИРУСНОЙ ИНФЕКЦИЕЙ 2019 (COVID-19) У ЛИЦ В ВОЗРАСТЕ ОТ 5 ДО 11 ЛЕТ (/media/154069/download)	5 - 11 years of age	Русский (Russian)
(October 29, 2021)		
ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ О ВАКЦИНАХ COMIRNATY (мРНК-ВАКЦИНЕ ПРОТИВ COVID-19) И ВАКЦИНЕ PFIZER-BIONTECH COVID-19 ДЛЯ ПРЕДОТВРАЩЕНИЯ ЗАБОЛЕВАНИЯ КОРОНАВИРУСНОЙ ИНФЕКЦИЕЙ 2019 (COVID-19) (/media/144624/download)	12 years of age and older	Русский (Russian)
(October 29, 2021)		
BAKUNA IMPORMASYON FACT SHEET PARA SA MGA TUMANGGAP AT MGA TAGAPAG-ALAGA TUNGKOL SA PFIZER-BIONTECH COVID-19 BAKUNA UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) PARA SA PAGGAMIT SA MGA INDIBIDWAL 5 HANGGANG 11 TAONG GULANG (/media/154071/download)	5 - 11 years of age	Tagalog (Tagalog)
(October 29, 2021)		
FACT SHEET NG IMPORMASYON SA BAKUNA PARA SA MGA TANGGAP AT CAREGIVERS TUNGKOL SA COMIRNATY (COVID-19 VACCINE, mRNA)AT BAKUNA NA PFIZER-BIONTECH COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) (/media/144663/download)	12 years of age and older	Tagalog (Tagalog)
(October 29, 2021)		
BẢNG THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ VẮC XIN PFIZER-BIONTECH COVID-19 NHẰM PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) ĐỂ SỬ DUNG CHO CÁ NHÂN TỪ 5 TỚI 11 TUỔI (/media/154074/download)	5 -11 years of age	Tiếng Việt (Vietnamese)
(October 29, 2021)		

Fact Sheet	Vaccine Recipient Group	Language
TỜ DỮ KIỆN THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ COMIRNATY (VẮC XIN COVID-19, mRNA)VÀ VẮC XIN PFIZER-BIONTECH COVID-19 ĐỂ PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) (/media/144626/download) (October 29, 2021)	12 years of age and older	Tiếng Việt (Vietnamese)
2019-YIL KORONAVIRUS KASALLIGINING (COVID-19) OLDINI OLINISH UCHUN PFIZER-BIONTECH COVID-19 VAKSINA HAQIDA UNI OLUVCHILAR VA ULARNI PARVARISHLAYDIGAN SHAXSLAR UCHUN VAKSINA HAQIDA MA'LUMOTLAR VARAKASI 5 DAN 11 YOSHGACHA (/media/153841/download) (October 29, 2021)	5 -11 years of age	O'zbek (Uzbek)
QABUL QILUVCHILAR VA PARVARISH QILUVCHILAR UCHUN COMIRNATY (COVID-19 Vaksina, mRNA) VA PFIZER-BIONTECH COVID-19 VAKSINASI KORONAVIRUS 2019 (COVID-19) KASALLIGINI OLDINI OLISH UCHUN Vaksina HAQIDA MA`LUMOT VARAQASI (/media/153841/download) (October 29, 2021)	12 years of age and older	O'zbek (Uzbek)

EXHIBIT E

Konkoly, Antonia (CIV)

From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, December 8, 2021 4:23 PM
To: Enlow, Courtney D. (CIV)
Cc: Elizabeth Brehm; Gabrielle Palmer
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon, Courtney,

Thank you for the response. Four hopefully simple questions/requests:

1. You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?

2. For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.

3. Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."

4. Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?

Best regards,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Thursday, December 2, 2021 2:25 PM
To: Aaron Siri <aaron@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron,

With regard to your first two questions, FDA will not be able to make those assessments at this time. In order for FDA to determine (1) the number of lines of spreadsheet data or (2) the total number of pages for each line of the 87-page Index, FDA would need to perform a search by hand. In other words, an individual would have to click open each file listed on the 87-page Index to determine the size of the file, and then manually record the file's size. To perform that search for the number of lines of spreadsheet data, FDA estimates that it would take 1.5 days of a staff member's time; to provide the page counts for each entry in the Index, FDA estimates that it would take several days of a staff member's time. Due to the heavy burden such an effort would place on FDA's limited resources, it is not feasible for FDA to provide those estimates.

With regard to your third question, are you asking whether there is any data in the Comirnaty biological product file that are not accounted for in the Index or the estimated 329,000+ page count? If so, the Cominarty biological product file also contains supplements, amendments, and product correspondence. FDA estimates that there are approximately

39,000 pages of records in that category. In addition, there may be investigational new drug records that may be supportive of the BLA. Although FDA cannot provide a precise count at this time, FDA estimates that there would be tens of thousands of additional pages in this category. These page counts are in addition to FDA's estimate of 329,000+ pages (plus data files) in the original Cominarty BLA.

If Plaintiff is amenable to the schedule I proposed yesterday, please let me know this week so that we can inform the Court.

Thanks,
Courtney

Courtney Enlow
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From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, December 01, 2021 5:56 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: [EXTERNAL] RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Courtney,

Thank you for the note. In order for me to have a meaningful conversation with my client, can you please let me know (1) approximately how many lines of spreadsheet data would need to be processed, (2) the approximate total number of pages for each line item in the Index of Comirnaty BLA you previously provided (copy attached) and (3) what else is in the biological product file for Comirnaty that is not reflected in the attached and is that included in the estimated 329,000 page count (and if not, how many pages does that consist of).

Thank you,
Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Wednesday, December 1, 2021 8:35 AM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good morning Aaron,

With regard to *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.), FDA has now had the opportunity to assess the number of responsive pages and to estimate processing times for additional portions of Plaintiff's priority list. In light of that assessment, FDA proposes that it produce the non-exempt portions of the following records by the below dates:

- By December 13, 2021, FDA plans to produce publicly releasable information from:
    - ***Plaintiff's priority item #1***- CRF files for site 1055 (~2,030 pages);
    - ***Completion of Plaintiff's priority item #5***-
        - Four additional .txt files that were listed on p. 10 of the index;
        - Four additional SAS files (not specifically listed on Plaintiff's priority list, but mentioned as something Plaintiff was interested in).
    - Publicly releasable information from the following additional sections of the original Comirnaty BLA:
        - Section 2.5 – Clinical Overview (~333 pages)
        - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
        - Section 2.7.4 – Summary of Clinical Safety (~344 pages)
- By December 30, 2021, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, FDA plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Under this schedule, by the end of January 2022, FDA expects to have produced publicly releasable information from more than 12,000 pages of records and 10 unpaginated .txt or SAS data files. (This page and file count includes records produced to Plaintiff on November 17, 2021, and records that will be produced to Plaintiff later today.) FDA will also have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

After the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling a minimum the non-exempt portions of 500 pages. (For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.) To the extent feasible, FDA plans to continue to prioritize records from Plaintiff's priority list. Although FDA proposes a minimum rate of 500 pages a month, FDA will continue to produce records at a faster rate where feasible.

Please let me know if Plaintiff is amenable to this proposed schedule. If so, I propose that the parties file a joint status report setting out the agreed-upon schedule and requesting that the Court cancel the hearing set for December 14 and the briefing deadlines.

Thanks,
Courtney

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From: Enlow, Courtney D. (CIV)
Sent: Wednesday, November 17, 2021 1:40 PM
To: Aaron Siri <aaron@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>
Subject: PHMPT v. FDA, No. 21-cv-1058 (N.D. Tex.)

Good afternoon Aaron and Gabrielle,

I've attached correspondence from FDA and a release of records in *PHMPT v. FDA*, No. 21-cv-1058 (N.D. Tex.). Kindly confirm receipt.

Thanks,
Courtney

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EXHIBIT F

Konkoly, Antonia (CIV)

From: Konkoly, Antonia (CIV)
Sent: Friday, December 10, 2021 8:57 PM
To: Aaron Siri; Elizabeth Brehm; Gabrielle Palmer
Cc: Enlow, Courtney D. (CIV)
Subject: PHMPT -- conferral questions

Hi Aaron et al –

I assume you saw the NOA that I entered earlier this week; I'm a colleague of Courtney's and will be handling the hearing on Tuesday. I look forward to working with you. We've conferred with FDA regarding the various questions you've posed; please see below the agency's responses, in red.

1.) **You claim it would take 1.5 days to determine the number of lines in the 126 data files, each similar to a spreadsheet. That estimate is difficult to understand since I would imagine it would require no more than someone opening each file, recording the total number of lines for each one, and then adding up the total number of lines. A paralegal at our firm could accomplish that task in less than an hour. Please explain why it would take 1.5 days to open each file and record the total number of lines in each file?**

   - First, FDA derived the number 126 came from its search of a specific portion of the BLA file (within Section 5). However, FDA expects that there are data files in other sections of the application, so 126 is likely not the full number of SAS files for the entire BLA. Accordingly, some the time estimate accounts for the time that would be needed to search for and locate other files. Additionally, SAS files are large and can present technical difficulties for FDA staff to open and navigate. Both search time and expected technical difficulties are thus accounted for in the 1.5 day estimate.

2.) **For the data files, please provide the column headers. My client would like to see these to determine if there is anything that can be streamlined.**

   - Due to the same technical difficulties noted above – which, on the ground, would make this task quite time-consuming – FDA is not able to accommodate this request at this time. In short, the diversion of time this would involve would meaningfully undermine the agency's ability to focus on its processing work.

3.) **Please provide a more precise number for the category you indicated has "tens of thousands of additional pages."**

   - FDA knows that there are a number of records in the IND section of the biological product file; however, it would take a closer review of those pages to determine which information would be considered supportive of the BLA/licensure and, thus, publicly available (subject to disclosure review) under 21 C.F.R. 601.51(e).

     You may already be aware of this, but to make sure we're on the same page – IND files may include studies for several forms (different dose strengths, formulations, etc.) and/or indications (different disease conditions, age groups, etc.). It's possible for a biological product to be approved for only a subset of the variations/indications for which it was originally studied. The portions of the IND file related to the approved conditions would become part of the biological product file that would be available for disclosure (subject to confidentiality review) once the product is approved; portions of the IND related to unapproved forms/indications would remain confidential (as would the existence of these portions).

To be clear, FDA disclosure staff have not yet determined whether portions of the IND section of the Comirnaty file refer to forms or conditions that are have not been approved under a BLA. Thus, this response should not be understood as an indication that any parts of the biological product file relate to INDs associated with a product that has not been approved. But, before performing that review (which would require a substantial investment of time from FDA), we cannot provide a precise page estimate. Because, again, the FDA assesses that that this effort does not justify the diversion of resources away from its processing work, it also cannot accommodate this request at this time.

4.) **Would the FDA be interested in hiring qualified unpaid volunteers to assist with reviewing the documents requested by PHMPT?**

- This is not an option. Non-federal personnel – whether they be unpaid volunteers, or per your later question, persons paid by the Plaintiff – cannot perform federal work.

5.) **Provide a list of the sections of the index that were not disclosed in the PDF index you provided.**

- FDA provided the high-level breakout of the entire original Comirnaty BLA. (See p. 1 of the Index provided on 11-4-21.) However, in accordance with the purpose of the index—ie, to assist PHMPT in honing in on the portions of the BLA that it is most interested in—FDA did not expand the index as to Sections that were not identified by PHMPT's Priority List. Additionally, other sections could not be expanded because to do so could have revealed confidential information.

6.) **An index for the documents in the BLA file that were not included in the index already provided (meaning, an index of the material that was not submitted as part of Comirnaty BLA application). The FOIA request, on its face, was for more than just the Comirnaty BLA submitted by Pfizer.**

- Creating the requested index would require FDA to create screen shots for each section, as it did for the index it provided in November. Given the nature of the documents in these sections, FDA anticipates that there would likely be confidential information in section titles, such that they could not be shared with PHMPT. Again, FDA assess that it cannot reasonably divert resources away from its processing efforts to this task at this time, in light of those circumstances.

Thanks,
Toni

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