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

PLAINTIFF'S COMBINED MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

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Public Health and Medical Professionals for Transparency ("**PHMPT**" or "**Plaintiff**") respectfully submits this Opposition to the Food and Drug Administration's ("**FDA**") Motion for Summary Judgment and in Support of PHMPT's Cross-Motion for Summary Judgment. This matter concerns a Freedom of Information Act ("**FOIA**") request submitted by PHMPT to FDA seeking copies of all data and information for Pfizer's COVID-19 Vaccine (the "**Pfizer Vaccine**"), licensed for those 16 years of age and older.

INTRODUCTION

The sole issue before the Court is an easy, clear-cut one: FDA, understanding full well from the outset that Plaintiff is seeking all records in FDA's possession concerning and leading up to the licensure of the Pfizer Vaccine, secretly withheld from Plaintiff an entire "EUA file"[1] containing approximately one million pages of responsive and critical records. This file contains the data that support FDA's decision to initially grant authorization and then licensure for the Pfizer Vaccine and to begin the world's largest vaccination campaign in history. There was only one clinical trial for one product, the Pfizer Vaccine, and around half the data and records related to that trial have been produced while the other half of the data and records remains hidden in the EUA file. This makes it impossible to properly analyze the clinical trial FDA relied upon to license this product, continuing FDA's refusal to simply provide transparency.

Only due to a specific document in a separate litigation, and through emails with opposing counsel in that separate litigation, was the existence of the EUA file first disclosed. FDA is well aware that this is the file that Plaintiff seeks yet mentions it in only *one* paragraph in its nearly 20-page brief (Defendant's Brief in Support of Motion for Summary Judgment, Dkt. 91, hereinafter "**Def. Brief**," at 15) and in only *one* nearly identical paragraph of the Declaration of Suzann Burk

[1] "EUA" means emergency use authorization.

("**Burk Decl.**") ¶ 42 of Defendant's App'x 013 ("**Def. App'x __**"). Instead of confronting the sole adequacy of search issue head-on, FDA attempts to distract with voluminous and sometimes irrelevant details about the records it *did* search for and produce. However, FDA is not permitted to unilaterally narrow requests or cherry-pick responsive documents regardless of the number of those cherry-picked documents and has, thus, failed to meet its statutory obligations under FOIA.

To be clear, Plaintiff seeks the EUA file as part of its FOIA request so that independent researchers can adequately evaluate the Pfizer Vaccine. Therefore, it is again worth stressing that there was *only one clinical trial* that FDA relied upon to license the Pfizer Vaccine. The data for this one trial is split between the EUA file (from an earlier point in time) and the remainder of what has already been produced (submitted to FDA by Pfizer at a later point in time). As PHMPT's scientists have repeatedly advised, and more recently bemoaned, they cannot do any real analysis with only half the data from this *one* trial for this *one* product. They need it all.

Since the independent researchers and scientists within PHMPT (and without) cannot conduct the analyses they need to conduct without this EUA file, we would be remiss if we did not make abundantly clear that this FOIA request is currently the *only* vehicle by which the American public will obtain access to these records. Pfizer (and Moderna) are not even considering requests for their data for at least 2 years post-trial, if ever. Whether they ever make this data available to the public is at their sole discretion. Perhaps revealing Pfizer's intent, its COVID-19 vaccine clinical trial study listing on the clinicaltrials.gov website states: "**Plan to Share Individual Participant Data** (IPD)? **No**."[2] The same American public who was convinced, coerced, and mandated to receive this product by their government deserve to see what the government saw and to know what the government knew. Simply because time has passed, the importance of these

[2] https://clinicaltrials.gov/study/NCT04368728#more-information (emphasis added).

records and what they reveal about the government's actions has not lessened, and nor should the urgency with which they are released to the public. In fact, FDA's effort to stonewall their release should only serve as a stark reminder of why FOIA exists in the first place.

Unfortunately, from the outset of this FOIA request, FDA, to the extent it could, has sought to obfuscate, delay, evade, and object to the release of the records at issue, and a part of this plan has clearly been to hide the existence of the "EUA file" until continuing that ruse became impossible. This conduct sadly continues to thwart the release of records to which the American public is entitled. FDA's lack of transparency and violations of FOIA should not be permitted and, thus, Plaintiff moves for summary judgment and an order from this Court that FDA produce the "EUA file" and any other responsive records forthwith.

FACTS

Procedural History

Plaintiff recognizes that the Court is familiar with the procedural history in this case and will therefore only recite those portions most critical for the instant motion.

On August 23, 2021, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty, (the "**Pfizer Vaccine**") for individuals 16 years of age and older.

Four days later, on August 27, 2021, Plaintiff submitted its FOIA request for "All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[3] with the exception of

[3] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

publicly available reports on the Vaccine Adverse Events Reporting System[4]" and sought expedited processing.

After FDA denied expedited processing, Plaintiff sued on September 16, 2021. The parties then briefed the timing of the production wherein Plaintiff sought an expedited production and FDA sought at least 75 years to produce the then-undisclosed volume of records.

During the litigation, FDA was not forthcoming about the number of pages responsive to the request. In November 2021, that number was originally cited as approximately 329,000 pages. (Dkt. 18, Dkt 22.) In December 2021, Plaintiff advised the Court that FDA had clarified that in addition to that previous number, there were another "approximately 39,000 pages" of BLA "supplements, amendments, and product correspondence," plus "tens of thousands of additional pages" of "records that may be supportive of the BLA," plus at least 126 data files. Plaintiff's best estimate of the volume of responsive pages at that time was 451,000 pages. (Dkt. 31.) On January 6, 2022, the Court issued its Order calling for production of 55,000 pages a month starting on March 1, 2022, which was presumably based on the 450,000 pages representation as it would have meant production would be complete by the end of that calendar year. (Dkt. 35.) Months later, in March 2023, Plaintiff informed the Court that while it had expected only around 450,000 pages, FDA had produced 779,206 as of that date and said there were still about 372,000 additional pages. (Dkt. 67.) It turns out that FDA knew at least *a year earlier than that*, by March 2022, that there were at least 1.2 million pages to review. Plaintiff did not learn this from FDA, but from a separate FOIA request submitted by Plaintiff which produced a contract between FDA and a third-party

[4] For the avoidance of doubt, this request includes **but is not limited to all of the data and information in the biological product file**, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

document reviewing company. (*PHMPT v. FDA*, 22-cv-00915 (N.D. Tex.) ("***PHMPT 2***"), Dkt. 28 at 1, April 12, 2023.) While FDA knew the volume it intended to produce by March 2022, it was never transparent about this fact with Plaintiff or the Court.

FDA produced documents monthly and on November 1, 2023, it represented that production was complete with a total of 1,187,147 pages processed. At that time, there was confusion among PHMPT's members as to certain data that was expected and needed but not received.[5]

On March 13, 2024, after conferring with members of PHMPT who are involved in analyzing the records produced, undersigned counsel sent a letter to FDA challenging the adequacy of the search. That letter listed seven categories of the most pressing records that PHMPT was still seeking that are needed in order to carry out crucial analyses and that PHMPT expected it would have received as part of the production as the records would have been in FDA's possession. (*See* Appendix, Declaration of Elizabeth A. Brehm (hereinafter "**Brehm Decl.**"), Exhibit A, App'x 003-141.) Note that at the time this letter was sent, PHMPT was not aware of any "EUA file" and assumed all records about the product's clinical trial would be contained within the product's file at FDA.

Prior to that letter, on January 2, 2024, FDA represented that production of the Pfizer 12-15-year-old portion of the *PHMPT 2* request was complete.[6] (Brehm Decl., Exhibit B, App'x 142-144.) The deGarays, plaintiffs in the *PHMPT 2* case, identified that their daughter's case report

[5] As an important example, the production contained PDFs with tables that were submitted with the biologics license application, and it also contained the underlying data for those PDFs/tables. The production similarly contained PDFs with tables that were submitted earlier on in the clinical trial with Pfizer's request for emergency use authorization, yet the data underlying those PDFs/tables was not produced. Thus, PHMPT cannot replicate those tables.

[6] The production of Moderna records is still ongoing.

form ("**CRF**") had not been produced despite FDA's claim that production was complete. Thus, on April 23, 2024, following emails with defense counsel, Plaintiff's counsel formally requested that the CRF be produced in *PHMPT 2*. (Brehm Decl., Exhibit C, App'x 145-146.) On April 24, 2024, counsel for FDA in *PHMPT 2* represented, *for the very first time in either of the litigations*, that there was something called an "EUA file" and that the CRF for the deGarays' daughter was in that file. FDA claimed the EUA file is separate from the "biological product file" and therefore was not responsive to Plaintiff's request and so it was not produced. (Brehm Decl., Exhibit D, App'x 147-149.) That was the first time Plaintiff was made aware of the existence of an "EUA file."[7]

On July 17, 2024, FDA responded to PHMPT's adequacy of search letter, referencing for the first time in *this* litigation the existence of an "EUA file." (Brehm Decl., Exhibit E, App'x 150-155.) FDA's letter, however, is unclear as to whether FDA does not have the seven categories of documents PHMPT asserts were missing from the production or if it *does* have the records but refuses to disclose them because they are in the newly identified "EUA file" which FDA deems "non-responsive" to the request. In conversations with FDA's counsel subsequent to this letter exchange, Plaintiff has learned that there are approximately one million pages of records related to the Pfizer Vaccine and its clinical trial in this EUA folder, none of which FDA has disclosed.

This EUA file is the file PHMPT seeks and that FDA continues to withhold – meaning, more than 3 years and 2 months have passed since the clinical trial documents were requested, and

[7] In *PHMPT 2*, the parties subsequently met and conferred about this issue, but FDA asserted this was not ripe to raise with the Court yet as production continues for Moderna. Counsel agreed in good faith to submit a separate FOIA to obtain the CRF but did not waive the argument that the CRF is responsive to the original request, which can be raised later in that litigation.

Plaintiff has received only half the records for the clinical trial Pfizer conducted and which it submitted to FDA to obtain a license for its COVID-19 vaccine.

Pfizer Vaccine Background and Relevant Regulation

The EUA file was plainly part of PHMPT's request for "All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)."[8] The regulation cited within the request, 21 C.F.R. § 601.51, is an FDA regulation that deals with the "confidentiality of data and information in applications for biologics licenses." The regulation was enacted in 1974.[9]

At the time it was enacted, the federal register read as follows:

> [A] biologic must be licensed by the Food and Drug Administration before it may lawfully be shipped in interstate commerce.[10] **Unlike the regulation of human and animal drugs, all biological products are required to undergo clinical testing in order to demonstrate safety, purity, potency, and effectiveness prior to licensing, regardless whether other versions of the same product are already marketed** or standards for the product have been adopted by rule making. Indeed, many of the existing standards require specific clinical testing before approval will be granted. This is required because all biological products are to some extent different and thus each must be separately proved safe, pure, potent,

[8] The request, in its entirety, also said, "with the exception of publicly available reports on the Vaccine Adverse Events Reporting System" and it contained two footnotes. The first footnote quoted the language of 21 CFR § 601.51(e). The second footnote, importantly, said, "For the avoidance of doubt, this request **includes but is not limited to all of the data and information in the biological product file**, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." PHMPT was making clear that it wanted **all** records about the Pfizer vaccine ("not limited to all of the data and information in the biological product file") except publicly available VAERS data.

[9] Although it has been amended since 1974, none of the amendments have been substantive. *See* https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-601/subpart-F/section-601.51 (showing amendments that address changes of addresses or of names of agency branches or that clarify that persons wishing to request the information shall submit a request under the Freedom of Information Act).

[10] Note that this recognizes licensure as the only way a biologic "may lawfully be shipped in interstate commerce." That is because, as explained further *infra*, emergency use authorization did not exist at the time and was therefore not an avenue for a biologic to be lawfully in use.

> and effective. Although, like an approved NDA, a license to manufacture a particular biologic is a private license that is applicable only to a single manufacturer, **a biologics license is under no circumstances granted by the Food and Drug Administration to a second manufacturer based upon published or otherwise publicly available data and information on another manufacturer's version of the same product**. Under section 351 of the Public Health Service Act, biologics never become "old drugs'' and cannot be marketed solely on the basis of an existing product standard published in the Federal Register. There is no such thing as a "me-too" biologic.
>
> Thus, the regulatory scheme for biologics is quite different from the methods by which new drugs and antibiotic drugs are controlled …
>
> Accordingly, the Commissioner concludes that **the safety and effectiveness data for a biologic regulated under section 351 of the Public Health Service Act is not properly classified as a trade secret. Such data afford no competitive advantage because, unlike the situation with new drugs, no competitor can utilize it to gain approval for his product.** Moreover, since such data are routinely published in the scientific literature, they do not fall within the confidential commercial information exemption…

Because there was not a concern for competitive advantage as there might be with drugs, FDA adopted the regulation – cited by PHMPT in its FOIA request – that mandates transparency of the data related to biological products (vaccines), including data about their clinical testing.

The definition of "biological product file" within the relevant regulation is:

> For purposes of this section the **biological product file** includes **all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions**. The availability for public disclosure of any record in the biological product file shall be handled in accordance with the provisions of this section.

21 CFR § 601.51(a).

To be sure, the term "emergency use authorization" or "EUA" does not appear within the definition of a "biological product file." That is because the regulation was drafted in 1972 and

enacted in 1974 – decades before "emergency use authorization" existed. Emergency use authorization was brought about in July 2004 as part of the "Project BioShield Act of 2004"[11] Thus, it could not have been specified within the regulation. Instead, the regulation uses a catch-all phrase ("and other related submissions") to capture additional data related to the biological product.

Reinforcing that the definition of "biological product file" is meant to include all data about the product, and crucial to the issue before the Court, 21 CFR § 601.51(g) states: "For purposes of this regulation, **safety and effectiveness data include *all* studies and tests of a biological product on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.**" 21 CFR § 601.51(g) (emphasis added).

There was only **one set of studies/testing done on this product** at the pre-clinical (animal testing) and clinical (Phase I trial, one Phase II trial, and one Phase III trials) testing stages. The study is described by Pfizer as follows:

> [A] Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in healthy individuals.
>
> The study consists of 2 parts: Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part.
>
> The study will evaluate the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate:
>
> - As a 2-dose (separated by 21 days) schedule;

[11] PROJECT BIOSHIELD ACT OF 2004, 108 P.L. 276, 118 STAT. 835. https://www.congress.gov/108/plaws/publ276/PLAW-108publ276.pdf. President George W. Bush signed the Act into law to improve medical countermeasures protecting Americans against a chemical, biological, radiological, or nuclear attack. Part of the Act "[ga]ve FDA the ability to make promising treatments quickly available in emergency situations – this tightly controlled new authority will enable access to the best available treatments in the event of a crisis." https://georgewbush-whitehouse.archives.gov/infocus/bioshield/index.html.

> - At various different dose levels in Phase 1;
> - As a booster;
> - In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55 or >55 years of age]).
>
> The candidate selected for efficacy evaluation in Phase 2/3 is BNT162b2 at a dose of 30 µg.
>
> Participants who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study.[12]

Thus, there were not separate studies or clinical trials for the "EUA" biological product versus the licensed biological product; there was animal testing and there was *a* clinical trial for the sole biologic product file at issue in this request: the Pfizer Vaccine. Pfizer first submitted data to FDA on November 20, 2020, seeking emergency use authorization for its COVID-19 vaccine.[13] This submission occurred as the clinical trial was ongoing. The EUA was granted just twenty-two days later on December 11, 2020 (a process that typically takes at least 6-10 months). About 5.5 months later, on May 7, 2021, Pfizer started another rolling submission seeking licensure for the same COVID-19 vaccine.[14] This submission added to the clinical trial data that Pfizer had previously submitted for the EUA.

In FDA's own words to the public at the time it granted licensure to the Pfizer Vaccine:

> For Comirnaty [Pfizer Vaccine], **the BLA builds on the extensive data and information previously submitted that supported the EUA**, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made… The first EUA, issued Dec. 11, for the Pfizer-BioNTech

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[12] https://clinicaltrials.gov/study/NCT04368728.

[13] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-emergency-use-authorization. Pfizer Press Release, November 20, 2020

[14] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics. Pfizer Press Release, May 7, 2021.

> COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals. **To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA** and included a longer duration of follow-up in a larger clinical trial population.[15]

It is clear that all of the data submitted leading up to FDA's decision to license the product, including any EUA data, is within the scope of the FOIA request.

LEGAL STANDARD

A movant is granted summary judgment "if the movant shows that there is no genuine dispute as to any material fact." FED. R. CIV. P. 56 (a). A material fact is a fact that "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). A genuine dispute arises "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id*.

"The moving party bears the burden of demonstrating [the] absence of a genuine issue of material fact in dispute." *Media Research Ctr. v. U.S. Dep't of Just.*, 818 F. Supp. 2d 131, 136 (D.D.C. 2011) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). An agency moving for summary judgment must prove that "it has fully discharged its obligations under the FOIA, after the underlying facts and the inferences to be drawn from them are construed in the light most favorable to the FOIA requester." *Id.* at 137.

Generally, courts limit their review to the information contained within the administrative record; however, the D.C. Circuit has held that supplemental evidence may be properly admitted:

> (1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency

[15] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (emphasis added). FDA News Release, August 23, 2021.

> considered evidence which it failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly; (5) in cases where evidence arising after the agency action shows whether the decision was correct or not; (6) in cases where agencies are sued for a failure to take action; (7) in cases arising under the National Environmental Policy Act; and (8) in cases where relief is at issue, especially at the preliminary injunction stage.

Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989) (footnote omitted). "Put another way, [c]ourts admit outside evidence primarily as a means of requiring an agency to explicate its own reasoning when the record is unclear." *Corel Corp. v. U.S.*, 165 F. Supp. 2d 12, 31 (D.D.C. 2001) (internal quotation marks omitted); *see* Brehm Decl., App'x 1-155.

ARGUMENT

PHMPT is entitled to summary judgment because there are no genuine issues of material fact. Conversely, FDA is not entitled to summary judgment because FDA has not proved, and cannot prove, it has fully discharged its obligations under FOIA. FDA did not conduct an adequate search and did not conduct the search in good faith. FDA has not advanced any logical, coherent reason as to why the EUA file does not fit the statutory definitions of the materials that must be released to the public. The EUA file concerning Pfizer's Vaccine is responsive to Plaintiff's request and Plaintiff therefore requests that the records within the file be produced with production complete no later than February 20, 2025.

"To meet its burden to show that no genuine issue of material fact exists, with the facts viewed in the light most favorable to the requester, the agency must demonstrate that it has conducted a 'search reasonably calculated to uncover **all** relevant documents.'" *Weisberg v. U.S. Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984) (quoting *Weisberg v. U.S. Dep't of Justice*, 227 U.S. App. D.C. 253, 705 F.2d 1344, 1350-51 (D.C. Cir. 1983)) (emphasis added); *see also Valencia-Lucena v. United States Coast Guard*, 180 F.3d 325 (D.C. Cir. 1999); *Defs. of Wildlife v.*

United States Border Patrol, 623 F. Supp. 2d 83, 91 (D.D.C. 2009). The standard of reasonableness "depends, not surprisingly, upon the facts of each case." *Weisberg*, 745 F.2d at 1485. Notably, FOIA obligates agencies to conduct searches in good faith. *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 551 (D.C. Cir. 1994) (quoting *Weisberg v. U.S. Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)).

To determine whether a search for responsive records was adequate, a court must first determine the scope of the documents the plaintiff requested. *Wallick v. Agric. Mktg. Serv.*, 281 F. Supp. 3d 56, 66 (D.D.C. 2017). It has long been established that an agency has a duty to construe FOIA requests liberally. *See Hemenway v. Hughes*, 601 F. Supp. 1002, 1005 (D.D.C. 1985); *Conservation Force v. Ashe*, 979 F. Supp. 2d 90, 101-02 (D.D.C. 2013); *Rodriguez v. DOD*, 236 F. Supp. 3d 26, 36-38 (D.D.C. 2017). Thus, an agency has a duty under FOIA to select the interpretation that would likely yield the greatest number of responsive documents. *Conservation Force*, 979 F. Supp. 2d at 102-03; *Nat'l Sec. Counselors v. CIA*, 849 F. Supp. 2d 6, 12 (D.D.C. 2012). "Technical precision" is not required in FOIA requests, "and a request certainly should not fail where the agency knew or should have known what the requester was seeking all along." *Inst. for Justice v. IRS*, 941 F.3d 567, 572 (D.C. Cir. 2019).

FDA cites *Batton v. Evers*, 598 F.3d 169, 176 (5th Cir. 2010) to argue that "[t]he issue is *not* whether other documents may exist, but rather whether the search for undisclosed documents was adequate." (Def. Brief at 9.) But *Batton* is not helpful to FDA here. In *Batton*, the plaintiff asserted that "other documents *may* exist that were not located in the search." *Batton*, 169 F.3d at 176. Here, Plaintiff *knows* that other documents exist because *FDA* knew and eventually disclosed that they exist. And so, as the *Batton* court held, the question is whether the search for the *undisclosed* documents was adequate. Here, FDA's search was by definition inadequate given that

FDA knows precisely where the records are and how to find them – yet, it did not conduct a search for them at all. In its brief, FDA explains: "The agency tracks EUA records in BIRAMS, and the IRA number associated with Pfizer's COVID-19 vaccine EUA file is 27034." (Def. Brief at 15.) Note that BIRAMS is also where FDA successfully searched for and pulled IND-related records from. (*See* Def. Brief at 13.) FDA purposefully overlooked the EUA file and interpreted the FOIA request in the most narrow, inartful reading possible to avoid producing known records.

SafeCard Servs., Inc. v. SEC, 926 F.2d 1197 (D.C. Cir. 1991) also does not support FDA's argument. FDA asserts that its affidavit should be "accorded a presumption of good faith, which cannot be rebutted by 'purely speculative claims about the existence and discoverability of other documents.'" (Def. Brief at 9.) But again, Plaintiff is not speculating about the existence and discoverability of other documents. FDA has confirmed a file of one million pages exists and knows precisely where that file is; there is no speculation needed.

Similarly, FDA cites numerous cases in an attempt to tell the Court that it should not interfere with the agency's administrative judgment in conducting its search. (*See* Def. Brief at 10.) But all of these cases presume that the agency has searched every reasonable place it would expect documents to be and yet the plaintiff challenges the search arguing there *may* be additional documents that were not disclosed or additional alternative methods the government should have applied. For example, in *Schrecker v. DOJ*, 349 F.3d 657, 662 (D.C. Cir. 2003), the court talks of the "agency's rate of success in unearthing the information sought." *Id*. at 662; Def. Brief at 10. Here, again, there is no need to "unearth" anything here. FDA was fully aware that Plaintiff wanted all records related to the Pfizer Vaccine. FDA knows there is an EUA file as well as a "biological product file" and so did not need to "unearth" anything. This is not a case where the Court can conclude that FDA did the best it could and while, yes, there *may* be other documents that exist

somewhere, we cannot expect the agency to check everywhere. Instead, this is a case where the FDA has a known file, filled with one million pages, about the sole product at issue that it has never disclosed to Plaintiff or to this Court throughout the entire production. A presumption of good faith in this circumstance would be inappropriate.

I. Plaintiff's FOIA Request Must Be Construed Liberally and the Scope Includes the EUA File

Here, FDA knew all along what PHMPT was after: all data FDA has concerning the Pfizer Vaccine that was licensed mere days before PHMPT submitted its request. Despite knowing this, FDA admits that when it received Plaintiff's request, it "[i]nitially …interpreted Plaintiff's FOIA Request as a 'request for all publicly releasable information *in the original biologics license application* submitted by BioNTech-Pfizer for the Comirnaty vaccine.'" (Burk Decl. at 7-8, Def. App'x 007-008 (emphasis added).) This, of course, was already an impermissible narrowing of Plaintiff's request with no explanation provided by the agency as to why it would unilaterally narrow an otherwise clear request. Throughout the parties' meet and confer calls from early on in the litigation, in the voluminous briefing submitted to the Court,[16] and during the Court hearings,[17]

[16] *See, e.g.*, Complaint (Dkt. 1 ¶ 21) (citing government claims the Pfizer Vaccine is 'safe and effective' made "prior to FDA approval"); *id.* ¶¶ 24-25 (citing article by member of PHMPT dated August 23, 2021 when "FDA [was on] the verge of granting a marketing license" to Pfizer discussing the inadequate EUA data and no reported data past March 13, 2021); *id.* ¶ 47 (making clear PHMPT seeks "full disclosure of the data and information underlying the FDA's conclusion that the Pfizer Vaccine is 'safe and effective.'"); Joint Status Report dated November 15, 2021 (Dkt. 20) ("Until the entire body of documents provided by Pfizer to the FDA are made available, an appropriate analysis by the independent scientists that are members of Plaintiff is not possible."); Plaintiff's Brief dated December 7, 2021 (Dkt. 26) (quoting President Biden talking about the need for "all of it" [the vaccine data] to be made "available to other experts across the nation so they can look and see, so there's a consensus this is a safe vaccine" and quoting fifteen U.S. Senators calling for "full transparency throughout the review and authorization process is [] essential…")

[17] *See* Transcript of December 14, 2021 hearing at 49 (Dkt. 34) ("In terms of the scope of documents. As the doctors have made very clear, **unless they have all the data, the entire production, they can't do a proper review. If even one data set is missing, they don't know if their analysis is correct**. In terms of the actual scope that was requested. As I pointed out, I believe

PHMPT was consistent and clear: with regard to the Pfizer Vaccine, PHMPT wanted to know what the government knew, see what the government had seen, and make that data publicly available so that independent researchers and scientists could run their own analyses to try to replicate what the government did or disprove the government's conclusions at the time it licensed the product. But throughout the processing of this request, FDA has attempted to impermissibly narrow the request and interpret it in the most restrictive way possible so as to produce the fewest number of responsive records.

To obtain the records, PHMPT clearly requested "All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)[18] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[19]"

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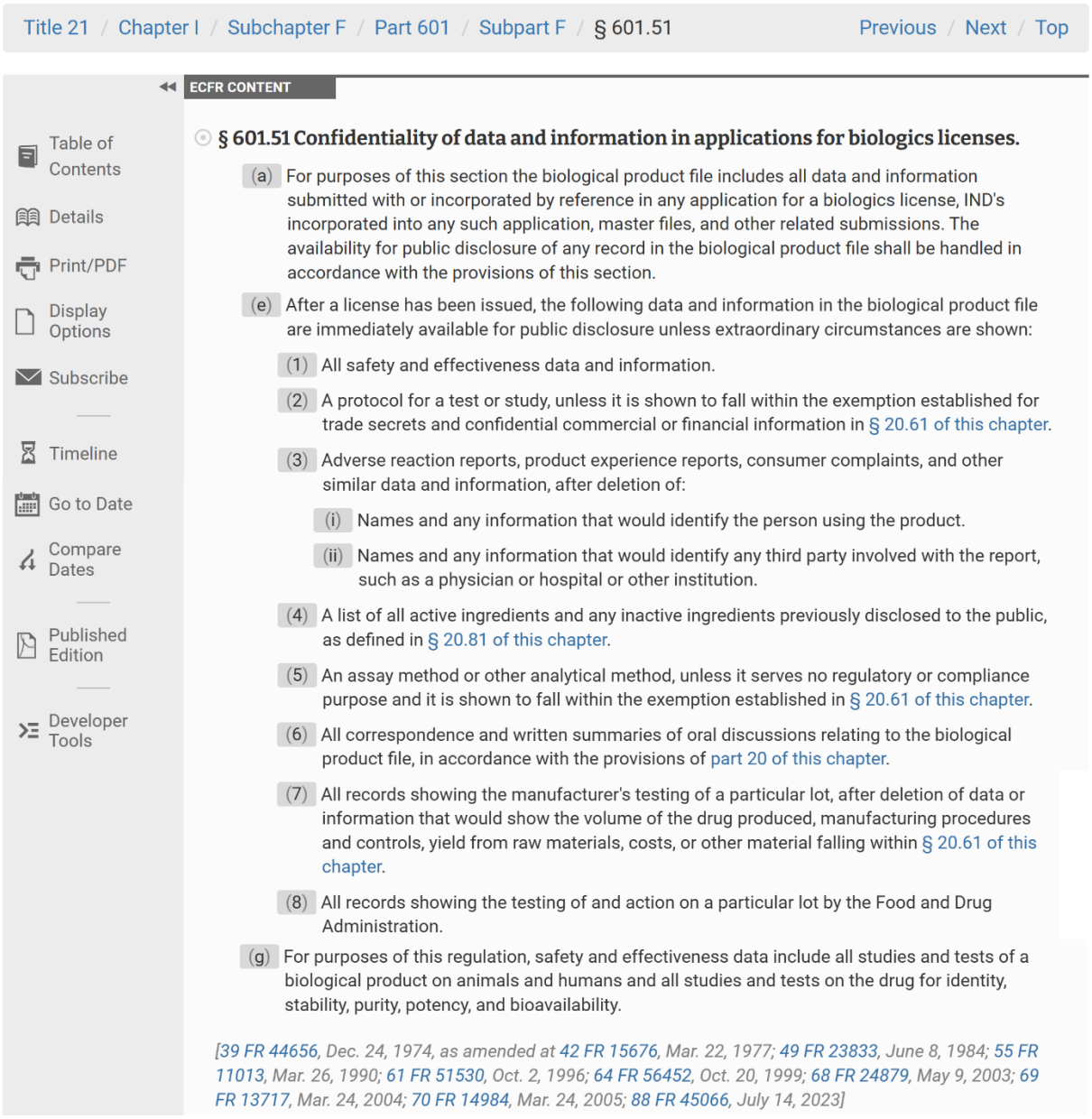
earlier, this FOIA request is for the precise scope of documents that the Code of Federal Regulations, that the FDA's own regulations say, should be made immediately available after licensure") (emphasis added); Transcript of January 28, 2022 hearing at 82 (Dkt. 58) ("as the group I represent has pointed out, until they get **all the documents** at issue here, **particularly the underlying data sets**, they can't do a proper analysis **because missing even one data set could throw off any analysis they do**.") (emphasis added).

[18] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[19] For the avoidance of doubt, this request includes **but is not limited to all of the data and information in the biological product file**, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

The relevant parts of the regulation referenced in the request read as follows:



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§ 601.51 Confidentiality of data and information in applications for biologics licenses.

(a) For purposes of this section the biological product file includes all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions. The availability for public disclosure of any record in the biological product file shall be handled in accordance with the provisions of this section.

(e) After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 20.81 of this chapter.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of part 20 of this chapter.

(7) All records showing the manufacturer's testing of a particular lot, after deletion of data or information that would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 20.61 of this chapter.

(8) All records showing the testing of and action on a particular lot by the Food and Drug Administration.

(g) For purposes of this regulation, safety and effectiveness data include all studies and tests of a biological product on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

[39 FR 44656, Dec. 24, 1974, as amended at 42 FR 15676, Mar. 22, 1977; 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 61 FR 51530, Oct. 2, 1996; 64 FR 56452, Oct. 20, 1999; 68 FR 24879, May 9, 2003; 69 FR 13717, Mar. 24, 2004; 70 FR 14984, Mar. 24, 2005; 88 FR 45066, July 14, 2023]

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Thus, the request language captures the EUA file now at issue.

[20] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-601/subpart-F/section-601.51 (excerpted to show only relevant sections of the regulation).

The request focuses on 21 C.F.R. § 601.51(e) which enumerates categories of "data and information in the biological product file" including, but not limited to, "all safety and effectiveness data and information." *See* image above.

Contrary to its obligation to construe this request liberally and to interpret it in the way that would yield the greatest number of responsive documents, understanding full well what Plaintiff was seeking, FDA puts its head in the sand, pretending to *not* understand what Plaintiff was seeking. It instead points to the definition of "biological product file" in subsection (a) of the regulation and then uses the definition as a restriction on the records it claims it was obligated to search. This argument must fail for at least three reasons.

First, because FDA knew what PHMPT was seeking, those records should have been disclosed. Period. A requester does not need to be precise and does not need to expressly name every record it seeks nor the location of where the records might be. FDA, as the government agency in control of the records, must take its understanding of the FOIA requester's goal and, in good faith, search for and produce those responsive records. *See Inst. For Justice v. IRS*, 941 F.3d 567, 572 (D.C. Cir. 2019) ("We do not require technical precision in FOIA requests, and a request certainly should not fail where the agency knew or should have known what the requester was seeking all along…**Nor do we require a requester to know anything about where or how the agency stores those [records]**." (emphasis added)).

Second, as noted *supra*, the regulation was enacted in 1974, decades before an "emergency use authorization" was created in 2004. Thus, the regulation's definition that the agency hyper-focuses on does not expressly provide an analogous path to licensure and only considers the application for a biologics license.

Third, and fatal to FDA's purposeful narrow reading of the request, subsection (g) of the regulation cited by Plaintiff defines the very "safety and effectiveness data" expressly and precisely requested by Plaintiff: "For purposes of this regulation, safety and effectiveness data include **all studies and tests of a biological product on animals and humans** and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability." 21 C.F.R. § 601.51(g) (emphasis added), *see* image above. The data within the EUA file that FDA is refusing to disclose is data about the same product for which it released the other 1.2 million pages. It is data about the same non-clinical (animal) studies and about the same clinical trial. To be sure, without the data in the EUA file, there would have been no licensure. In other words, the biologics license application was an extension of the request for emergency use authorization – the BLA data continued the already-submitted data from an earlier timepoint in the same trial. In FDA's own words: "[T]he BLA builds on the extensive data and information previously submitted that supported the EUA..."[21] The BLA, therefore, all rests on the EUA date; they are completely related and intertwined.

All of the data submitted by Pfizer to FDA in order to, first, obtain emergency use authorization and, subsequently, licensure, are responsive to PHMPT's request for "all data and information for the Pfizer Vaccine" which includes "all safety and effectiveness data and information," which is defined as "all studies and tests of a biological product on animals and humans…" To argue otherwise is to ask this Court to suspend reality.

[21] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine. FDA News Release, August 23, 2021.

II. Even If the Appropriate Focus Is on the Definition of "Biological Product File," the EUA File Is Still Responsive

FDA takes the position that the request must be read only literally and as narrowly as possible and, in so doing, it ignores subsection (g) of 21 C.F.R. § 601.51 and only looks to subsection (a) to govern its search parameters. This violates the agency's duties under FOIA. However, even if a technical reading of subsection (a) and the definition of "biological product file" is appropriate to determine the scope of the agency's search, Plaintiff still prevails.

Subsection (a)'s definition of biological product file (which FDA cannot and does not argue is excluded from Plaintiff's request) has at least two provisions which would encompass the EUA file.

First, the definition "includes all data and information submitted with or incorporated by reference in any application for a biologics license." The EUA file is and must be incorporated by reference in the biologics license. Again, as stated above, there was only one clinical trial for the Pfizer Vaccine. This is not a scenario where there was one product and one clinical trial that was submitted for EUA and then a separate product, with a separate clinical trial, then submitted for a license: it is the same product, tested in the same trial. The biologics license application built upon the foundation set by the prior request for emergency use authorization submitted to FDA. Evidencing this is that FDA's BLA Clinical Review Memorandum states ***"Supportive information from EUA 27034/0 and clinical study protocols reviewed under IND 19736 were also referenced during the review cycle***."[22] This shows that when FDA was reviewing Pfizer's application for a biologics license, it reviewed information from both the EUA and IND files. Thus, the EUA files were part of the review conducted by FDA in issuing licensure and so they are ipso facto part of

[22] FDA's BLA Clinical Review Memorandum, dated August 23, 2021 at 20, available at https://www.fda.gov/media/152256/download?attachment.

the overall biological product file.

Second, the definition "includes … other related submissions." Although the regulation at the time could not name "emergency use" submissions, given it did not yet exist, a plain reading of the regulation's definition lists everything else related to the biological product and makes clear that it meant to capture all submissions related to the biological product (listing all data existing at the time of enactment and "and other related submissions"). The "biological product file" is, after all, FDA's file about the biologic product. Again: same product for EUA and BLA, same trial. To argue that the emergency use authorization data is not "related to" the biological product file or to the application for the biologics license is nonsensical.

III. The EUA File Is Critical to PHMPT's Goals and to the American Public

Plaintiff is under no duty to proffer a reason why it seeks these records, other than to demonstrate that the records reveal information about our government's actions. *See Fed. Labor Relations Auth. v. United States Dept' of Treasury*, 884 F.2d 1446, 1451 (D.C. Cir. 1989) ("[U]nder FOIA the disclosure interest must be measured in terms of its relation to FOIA's central purpose -- to ensure that the *Government*'s activities be opened to the sharp eye of public scrutiny." (internal citations omitted)). These records unquestionably meet that criterion. However, it is important to note that there are multiple groups, some at major universities, as well as individuals working with the data being disclosed through this FOIA.

Some of those individuals have published books and articles,[23] in addition to other writings about the data, but various major university scientists and other scientific groups have yet to

[23] *See, e.g.*, https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/; https://www.amazon.com/DailyClout-Documents-Analysis-Volunteers-Reports-ebook/dp/B0BSK6LV5D?asc_source=01J4MHGGSBVSF6AFQ9RRJ9VTCE&tag=snxs21-20; https://www.amazon.com/Pfizer-Papers-Pfizers-Against-Humanity-ebook/dp/B0CNQGVDKB?asc_source=01J4MHGGSBVSF6AFQ9RRJ9VTCE&tag=snxs21-20.

publish as they are still waiting on all datasets. They still, all these years later, cannot move forward and replicate what the government reviewed to license this product without the data that they now know is in an "EUA file." They have made clear that this is the only route likely ever to obtain these data.

Nearly four years have passed since Pfizer applied for emergency use authorization from FDA. Since that time, approximately 80% of Americans have received a dose of a COVID-19 vaccine. Many of them were mandated to do so, either at the time of the emergency use authorization or at the time of licensure. All of them have funded the government's actions with regards to these products. They deserve today, no less than they did throughout the last four years, transparency. FDA cannot be allowed to continue to withhold data about this product by playing games and violating FOIA, which it has done since the inception of this FOIA request and which it continues to do to date.

CONCLUSION

For the foregoing reasons, the Court should deny FDA's motion for summary judgment, grant PHMPT's cross-motion for summary judgment, and order FDA to disclose, forthwith, the non-exempt portions of all remaining responsive records including the "EUA file," with production to be complete no later than February 20, 2025.

Dated: November 7, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2024, 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/ Elizabeth A. Brehm
Elizabeth A. Brehm