UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

**PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,**

Plaintiff,

v. **No. 4:21-cv-01058-P**

**FOOD AND DRUG ADMINISTRATION,**

Defendant.

## MEMORANDUM OPINION AND ORDER

Before the Court are Defendant Food and Drug Administration (the "FDA")'s Motion for Summary Judgment (ECF No. 90) and Plaintiff Public Health and Medical Professionals for Transparency ("Plaintiff")'s Cross-Motion for Summary Judgment (ECF No. 93). Having considered the briefing, evidence, and applicable legal authorities, the Court concludes that the FDA's Motion is **DENIED** and Plaintiff's Cross-Motion is **GRANTED**.

## BACKGROUND

On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 Vaccine (the "Pfizer Vaccine") for individuals sixteen years of age and older. Four days later, Plaintiff submitted a Freedom of Information Act ("FOIA") request with the FDA for "[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." In addition, Plaintiff's request included a footnote specifying that "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 . . . ." After the FDA denied Plaintiff's request for expedited processing, Plaintiff filed this lawsuit on September 16, 2021. On January 6, 2022, after being informed that the

FDA sought up to seventy-five years to produce the documents, the Court put the Parties on an expedited document production schedule which was partially modified on February 2, 2022. Since then, the FDA has produced some 1,200,874 pages of responsive records. The Parties now dispute the sufficiency of the FDA's search, and each moves the Court to grant summary judgment in their favor.

Vaccines are regulated as biological products under the Public Health Service Act ("PHSA") and as drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See* 42 U.S.C. § 262(i)(1); *see also* 21 U.S.C. § 321(g)(1)(B). Vaccines are approved for marketing through applications known as Biologics License Applications ("BLA"). *See* 42 U.S.C. § 262(a).

A sponsor of a biological product—such as a vaccine—generally begins the process of studying an investigational product by performing a variety of laboratory tests on it, including certain safety tests in animals. *See* ECF No. 92 at 5; *see also* 21 C.F.R. Part 58. The sponsor's focus at this stage is to collect the data and information necessary to establish that the investigational product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. ECF No. 92 at 5. However, before the investigational biological product may be administered to human subjects, the sponsor must first submit an investigational new drug application ("IND") to the FDA. *See* 21 C.F.R § 312.20; *see generally* 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. Part 312. In general, an IND application contains the: (1) results of the laboratory and animal tests that have been performed, gathered, and submitted by the sponsor; (2) manufacturing information for the investigational biological product; and (3) sponsor's plans for testing the investigational biological product on human subjects. *See generally* 21 C.F.R. § 312.23.

Tests conducted in human beings are called "clinical trials." The FDA's medical and scientific reviewers evaluate the data submitted in the IND, including the proposed clinical trial protocols. *See* ECF No. 92 at 6. If the reviewers determine, from the evidence, that the biological product does not pose an unreasonable or significant risk of illness or injury to human subjects and, if there are no other problems with the

submission that cause the agency to identify the need for a clinical hold, the agency will allow the clinical trial to proceed. *Id.* Given that an IND is submitted during the investigational stage of drug development, IND files may contain data and information regarding formulations, dosages, or uses that differ from those that are ultimately licensed. *Id.*

In a subsequent stage of the development process, sponsors may submit to the FDA a formal application for licensing (i.e., marketing approval), which is called a BLA. *See* 42 U.S.C. § 262(a)(1)(A). BLAs include various information and data, including: (1) nonclinical and clinical data; (2) information about manufacturing methods and locations; (3) data establishing stability of the product through the dating period; (4) summaries of results from tests performed on the lots of representative samples of the product; and (5) mockups of the labels, enclosures, medication guide if proposed, and containers as applicable. *See* 21 C.F.R. § 601.2(a). Pursuant to the PHSA, the FDA approves a BLA if the applicant has demonstrated that: (1) the vaccine is "safe, pure, and potent;" and (2) the facility in which the vaccine is produced meets standards designed to assure that the vaccine continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C)(i). The applicant must also consent to inspection of the manufacturing facility. *Id.* § 262(a)(2)(C)(ii).

If the FDA determines that the BLA meets the statutory and regulatory requirements, the FDA will issue a biologics license for the product, authorizing the sponsor of that particular BLA to market that new product. *See* 21 C.F.R. § 601.4(a). IND and BLA files continue to be maintained following initial licensure of a product, and sponsors may continue to make submissions to the relevant file. ECF No. 92 at 6. For example, clinical trial data for formulations, dosages, or uses that differ from the licensed vaccine could be submitted to the IND file; and certain post-licensure submissions for the licensed vaccine would be submitted to the BLA file. *Id.*

In addition to BLAs, as part of the "Project BioShield Act of 2004," Congress granted the FDA the ability to grant "Emergency Use Authorization" ("EUA") to certain medical products—such as vaccines—during public health emergencies. The purpose of the act is to allow the

"use of unapproved medical products . . . in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met." *See Emergency Use Authorization for Vaccines Explained*, U.S. Food and Drug Administration (Nov. 20, 2020), https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained. As a result, the level of scrutiny afforded to a vaccine seeking EUA approval varies significantly from what is considered normal for FDA approval. The standards for FDA approval vary depending on the type of medical product at issue; devices rarely require clinical trials, whereas drugs and biologics usually require randomized clinical trials proving safety and efficacy. *See* Diana Zuckerman, *Emergency Use Authorizations (EUAs) Versus FDA Approval: Implications for COVID-19 and Public Health*, (June 2021) https://pmc.ncbi.nlm.nih.gov/articles/PMC8101583/. Generally, EUA applications require data supporting—not proving—safety and effectiveness, with lower standards and faster reviews than normal FDA approval. *Id.* While it is normal for EUA standards to vary from those required for FDA approval the "EUA standards for COVID-19 products varied considerably" and, in some cases, did "not require[] any FDA review of safety or efficacy." *Id.*

## LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A dispute is "genuine" if the evidence presented would allow a reasonable jury to return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is "material" if it would affect the case's outcome. *Id.* Generally, the "substantive law will identify which facts are material," and "[f]actual disputes that are irrelevant or unnecessary will not be counted." *Id.*

Under Fifth Circuit law, an agency may demonstrate the adequacy of its search by showing that it used "methods which can be reasonably expected to produce the information requested." *Batton v. Evers*, 598 F.3d 169, 176 (5th Cir. 2010) (quoting *Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 68 (D.C. Cir. 1990)). The issue "is not whether there might exist

any other documents possibly responsive to the request, but rather whether the *search* for those documents was *adequate*." *Weisberg v. U.S. Dep't of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984) (emphasis in original). To demonstrate the adequacy of its search, the agency may submit affidavits or declarations explaining the scope and method of the search in reasonable detail and in a nonconclusory fashion. *Brown v. F.B.I.*, 873 F. Supp. 2d 388, 399 (D.D.C. 2012) (citing *Steinberg v. DOJ*, 23 F.3d 548, 551 (D.C. Cir. 1994)). These documents "are afforded a presumption of good faith, which cannot be rebutted by purely speculative claims about the existence and discoverability of other documents." *Id.* (citing *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C.Cir.1991)). Additionally, in making a determination a "district court must analyze all underlying facts and inferences in the light most favorable to the FOIA requester." *Freedom Coal. of Drs. for Choice v. Centers for Disease Control & Prevention*, No. 2:23-CV-102-Z, 2024 WL 69084, at *5 (N.D. Tex. Jan. 5, 2024) (quoting *Ayuda, Inc. v. Fed. Tr. Comm'n*, 70 F. Supp. 3d 247, 259 (D.D.C. 2014)).

## ANALYSIS

The briefing of the Parties makes clear that there is only one issue remaining in this case—whether the EUA file is responsive to Plaintiff's FOIA request and must be produced. For the reasons set out below, the Court finds that it is.

As discussed above, Plaintiff's FOIA request states: "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." *See, e.g.*, ECF No. 1-1 at 2. Plaintiff's request also contained two footnotes providing:

> (1) "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];" and
>
> (2) "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."

*Id.*

While the Parties debate numerous theories regarding the responsiveness of the EUA, the Court's analysis begins and ends with whether it was "submitted with or incorporated by reference" in the BLA. The FDA argues that the EUA file does not fall within Plaintiff's FOIA request because the BLA and EUA are separate applications that are subject to different standards and, thus, a FOIA request for one does not necessitate production of the other. ECF No. 97 at 3–11. While the FDA is correct that the two applications are distinct, it is evident to the Court that in this case, the EUA is disclosable data as requested by Plaintiff and defined in 21 C.F.R. § 601.51. Section 601.51 provides that "all data and information submitted with or incorporated by reference in any [BLA]," as well as "other related submissions" must be disclosed. *Id.* at § 601.51(a). Further, Section 601.51 provides that "[f]or the purposes of this regulation, safety and effectiveness data include[s] ***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." *Id.* at § 601.51(g) (emphasis added).

In an August 23, 2021 press release, the FDA stated, *inter alia*:

> For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. ***For [the 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 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. . . .

*FDA Approves first COVID-19 Vaccine: Approval Signifies Key Achievement for Public Health*, U.S. Food & Drug Administration (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (emphasis added) (hereinafter the "FDA Statement").

The FDA argues that its statement is insufficient to establish that the "data and information" from the EUA was "submitted with or incorporated by reference" in the Pfizer Vaccine's BLA because "the language merely alludes to the EUA file, and does not specifically identify any particular records from the EUA file that a reviewer intended to incorporate into their review of the BLA." ECF No. 98 at 6. Similarly, the FDA argues that the EUA is does not fall within the definition of "other related submissions." The Court disagrees.

In support of its argument that the EUA file was not incorporated by reference, the FDA cites to *Morley v. CIA*, 508 F.3d 1108 (D.C. Cir. 2007). In *Morley*, a journalist was seeking records related to the John F. Kennedy assassination. *Id.* at 113. As relevant here, the court held that the CIA was not required to search for and produce "records referenced in the responsive documents." *Id.* at 1121. The FDA relies on this case for the proposition that "mere reference to other files does not establish the existence of documents that are relevant to appellant's FOIA

request." *Id.* (quoting *Steinberg v. U.S. Department of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994)).

This case is easily distinguishable. Here, the FDA's statement provides that the BLA builds on the EUA's "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." FDA Statement. It further states that the BLA "updated data from the clinical trial which supported the EUA." *Id.* The FDA's statement evidences the fact that the EUA was not "mere[ly] reference[d]" in the BLA but that the BLA incorporated and relied heavily on the EUA. Thus, the Court finds that at a minimum, the EUA is an "other related submission" with regard to the BLA. Additionally, however, the EUA is responsive to Plaintiff's FOIA request under Section 601.51(a) as it was "submitted with or incorporated by reference" in the Pfizer Vaccine's BLA. Either way, the EUA must be produced. Therefore, it is **ORDERED** that Plaintiff's Cross-Motion for Summary Judgment is **GRANTED,** and the FDA's Motion for Summary Judgment is **DENIED**.

## CONCLUSION

"The liberties of a people never were, nor ever will be, secure, when the transactions of their rulers may be concealed from them." Jonathan Elliot, *The Debates in the Several State Conventions on the Adoption of the Federal Constitution, as Recommended by the General Convention at Philadelphia in 1787*, at 169–70 (ed. 1881) (statement of Patrick Henry). The Covid-19 pandemic is long passed and so has any legitimate reason for concealing from the American people the information relied upon by the government in approving the Pfizer Vaccine.

For the reasons set out above, Plaintiff's Cross-Motion for Summary Judgment is **GRANTED,** and the FDA's Motion for Summary Judgment is **DENIED**. It is **ORDERED** that the FDA shall produce the responsive EUA file **on or before June 30, 2025.**

**SO ORDERED** on this **6th day of December 2024.**

Mark T. Pittman
UNITED STATES DISTRICT JUDGE