UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

and

PATRICK AND STEPHANIE DE GARAY,

Plaintiffs,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:22-cv-915-P

PLAINTIFFS' REPLY IN SUPPORT OF THEIR BRIEF FOR TIMELY PRODUCTION SCHEDULE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Plaintiffs[1] submit this reply in further support of their motion for timely production:

INTRODUCTION

The central issue in this case is what constitutes transparency and the level of transparency the American people are entitled to regarding Covid-19 vaccines licensed by FDA.

FDA's lack of transparency on this front necessitated an order in PHMPT 1 to compel what was expected to be a timely production of the data relied upon by FDA to license Comirnaty (Pfizer's Covid-19 vaccine) for adults. As this Court has explained, untimely production thwarts transparency. Unfortunately, transparency was thwarted in PHMPT 1 because despite page numbers in the range of 300,000 to 400,000 used at least 27 times in briefing and argument in PHMPT 1, FDA just disclosed that the total number of pages is around 1.2 million.

Worse, FDA knew the real page count long ago but failed to disclose that information to PHMPT or to the Court. As we just learned from a FOIA production received a few days ago in a different matter, FDA, sometime prior to March 7, 2022 solicited and, on April 22, 2022, awarded a contract to comply with its production obligation in PHMPT 1 in which it made clear the review was for around 1.2 million pages.[2] Yet, up until a few weeks ago, FDA continued to maintain to PHMPT that it could not provide an approximate page count.

FDA also refused PHMPT's request from over a year ago to sequence the production in PHMPT 1 in a manner that would make the less-than-full production at least somewhat useful to the public. It now urges another attempt to thwart transparency by asking this Court to enter a production schedule here that will take a minimum of 23.5 years, likely longer. (Dkt. 27 at 11-13.)

[1] Defined terms used herein have the same meaning as in Plaintiffs' opening brief in support of a timely production schedule. (Dkt. 24.)
[2] *See* https://icandecide.org/wp-content/uploads/2023/04/nr_75F40122F19210-Signed-PR.pdf#page=6.

In defending this proposed schedule, FDA makes arguments against expedited processing and about overall agency resources. First, in adding expedited processing to FOIA, Congress made clear that expedition is appropriate where there is urgency to inform the public concerning Federal Government activity. *See* 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II). If release of documents concerning Covid-19 vaccines – which were the subject of the most massive vaccination campaign ever carried out in this country, and which were even promoted by FDA prior to licensure and mandated by the government – does not qualify as a compelling need, it is unclear what, if anything, ever would.

Second, as for lack of agency resources, FDA argues it is currently diverting funds that could be used to license other drugs. What the agency does not disclose, however, is that when pharmaceutical companies apply to license drugs, those pharmaceutical companies pay the agency fees.[3] It is also notable that the agency did not slow down emergency use authorization review or grants of same due to lack of resources. It did not slow down its approval process due to lack of resources. Nor did it slow down its promotion of these products due to a lack of resources. It did whatever it needed to do to get these vaccines approved, widely promoted, and into the arms of the American public. The agency's own regulation makes part and parcel of the approval process the "immediate release" of the data within the biologic product file. If the agency did not have the resources to satisfy that regulation as part of the approval process, then it should not have granted approval to these products. But it did. It did not let diversion of funds or concerns about other FOIA requesters get in its way. It purportedly moved the sun and earth to get these vaccines out into the nation and now it must do the same to get the relevant data out to the public. FDA was not legally obligated to make every possible effort to get these vaccines out into the nation

[3] *See, generally*, https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.

"immediately," but it did. Here, where the law *does* explicitly require FDA to "immediately" release data it already possesses, it should be made to take equal if not greater steps to do so.

While FDA is correct that "[t]his case is not a challenge to the decision of the [FDA] to approve the vaccines, and it is not about the legality or the wisdom of vaccination mandates," these governmental actions of authorization, approval, and mandates do go to the heart of why transparency is critical.[4]

FACTUAL BACKGROUND

Plaintiffs incorporate their previous arguments and factual support for their request (Dkts. 1, 24) and limit the below to clarifying the record regarding certain assertions made by FDA.

I. PARTIES' NEGOTIATIONS

Plaintiffs commenced this action on October 11, 2022. Prior to FDA filing an answer, the parties began discussions concerning the rate of production and the volume of responsive documents in this matter and in PHMPT 1. While counsel for FDA in this matter did not have this information, he acknowledged its importance in negotiating the production schedule for this case.

On January 23, 2023, the parties had their third meet and confer during which Plaintiffs requested index listings of the biologic product files at issue in this case,[5] but again critically explained they needed to know the approximate documents left to produce in PHMPT 1 as their request in PHMPT 2 was keyed to same. FDA counsel indicated that Plaintiffs should take the remaining pages and "divide by 55,000" to figure out how many months were left. Plaintiffs again

[4] An email sent from Dr. Gruber, a former FDA employee who left FDA after disagreeing with how the agency handled the review, authorization, and approval of Covid-19 vaccines, to Dr. Woodcock, the then-Acting Commissioner of FDA, states that Dr. Woodcock had shared her "opinion that, absent a license, states cannot require mandatory vaccination." It is plain that mandates were a relevant issue in FDA's review of these vaccines. https://icandecide.org/wp-content/uploads/2023/04/Comirnaty-Approval-in-the-Office-of-the-Commissioner.pdf#page=2.

[5] Although FDA had already produced this index with page-count listings for the Moderna vaccine in another litigation months earlier, on August 11, 2022, FDA did not produce it in this matter until February 6, 2023. *See Defending the Republic v. FDA*, No. 3:22-cv-01237-E (N.D. Tx. Aug. 16, 2022) (Dkt. 18 Joint Status Report).

pointed out that counsel in PHMPT 1 and FDA had refused to disclose any information about the remaining volume in PHMPT 1 and, therefore, they were unable to do this calculation.

While it was FDA that stonewalled Plaintiffs, FDA attempts to paint Plaintiffs as the party unwilling to negotiate and confer in good faith.[6] The truth is that in PHMPT 1, FDA's response to almost all of PHMPT's requests to streamline, sequence the production, or obtain information was that FDA could not accommodate the requests.

Based on its experience in PHMPT 1, PHMPT understands the importance of sequencing documents, having detailed indices, and knowing when the production in PHMPT I would be complete. Unfortunately, during the parties' subsequent meet and confer on this topic on January 27, 2023, and while refusing to provide the remaining volume in PHMPT 1, FDA's in-house counsel stated that the claim that FDA had not provided an estimated remaining volume in PHMPT 1 was "a conspiracy theory." This, of course, is nonsensical as FDA in fact had not provided this estimate including for weeks thereafter (in fact, not until March 15, 2023). In that moment it was clear the agency had no intention of engaging in good faith and the parties were at an impasse.

While Plaintiffs had to wait until March 15, 2023, FDA knew no later than April 4, 2022, that the production in PHMPT 1 was approximately 1.2 million pages. This is because two days ago, in response to a separate FOIA request, the undersigned obtained the contract FDA awarded on April 22, 2022 for an outside vendor to fulfill the production required by PHMPT 1 which stated: "The estimated page count of records is about 500,000 (pages not inclusive of data files (SAS) which are unable to be paginated)((40 rows equals 1 page, thusly, the data files to convert

[6] *See* Dkt. 27 at 11 ("However, after receiving the listings, Plaintiffs stated they were unable to engage in discussions about the BLA/sBLA and failed to ask a single substantive question about the BLA/sBLA listings or online materials about the types of records found in BLAs provided by FDA … Nor did Plaintiffs answer any of FDA's questions about what types of information they are most interested in.").

is about 700,000 pages)."[7] This total of 1.2 million pages could have and should have been shared with Plaintiffs as soon as it was known by the agency. Instead, Plaintiffs were made to wait almost a full year during which FDA claimed it could not estimate the volume of remaining documents.

II. REDACTIONS

A large part of the agency's claimed burden in PHMPT 1 and here is the "careful[] review" needed "to determine whether one or more FOIA exemptions apply." (Dkt. 27 at 8.) In PHMPT 1, where FDA represents it has produced 770,985 pages, only 514 of these pages contain (b)(4) redactions and only 660 pages contain (b)(6) redactions. This means that 0.15% of the pages reviewed and produced required, from the agency's perspective, redactions. Much of these redactions are also the same easily located data: dates of birth and death, contact information, signee names and signatures, etc., and they occur within similar file types. The review for exempt disclosure, while necessary, is not the near-impossible job the agency holds it out to be.

III. RESULTS OF PHMPT 1 PRODUCTION

FDA next argues that "Plaintiffs have not explained how the unfocused release of hundreds of thousands of pages of Comirnaty records…has informed the public in an effective manner." (Dkt. 27 at 17.) But as PHMPT has made clear from the beginning, to the agency and the Court, without the full release of all the data, they and other scientists would be unable to properly conduct any analyses. (*See, e.g.*, PHMPT 1 Dkt. 27 at 10, 14, 108, 164.)

FDA also refused, on April 7, 2022, PHMPT's request in PHMPT 1, that specific documents be prioritized to make the partial production somewhat useful, as detailed *infra* at Argument § II. FDA also refused a February 10, 2023 request in PHMPT 1 for early release of two specific documents that scientists had been waiting over a year to obtain to conduct certain

[7] https://icandecide.org/wp-content/uploads/2023/04/nr_75F40122F19210-Signed-PR.pdf#page=6.

analyses: the first contains "full details and outputs regarding deaths…for Phase 3" of the trial, and the second, as published in BMJ, is "a key analysis dataset known as ADSL (Subject-Level Analysis Data)" which "supported the creation of all other analysis datasets and must be run first before any other ADaM datasets; all other programs are depending on ADSL output."[8] As PHMPT members Drs. Doshi and Wastila have stated: "This means that replicating even the most basic safety and efficacy analyses that Pfizer presented in its reports is still not directly possible."[9] FDA just produced the ADSL file and still has not produced the first document concerning deaths.

The agency cannot have it both ways: take over two calendar years to produce the data in its own "unfocused," unorganized, unexplained fashion while refusing to discuss or accommodate any requested prioritization, and simultaneously argue that Plaintiffs have not used the incomplete data to inform the public. That precise issue is doomed to repeat itself here should the agency's proposal be accepted by the Court. Put plainly, if required to wait a minimum of 23.5 years, there will be nothing to effectively inform the public about with respect to these products.

ARGUMENT

I. EXPEDITED PROCESSING IS WARRANTED

If any FOIA requests to FDA qualify for expedited processing, it is the ones at issue here. First, FDA's own regulation expressly states that "[a]fter a license has been issued, the [] data and information in the biological product file are immediately available for public disclosure." 21 C.F.R. § 601.51. Hence, even if by FOIA, immediate release is the default. Second, as FDA acknowledges, compelling need to expedite can be shown by demonstrating that (1) the requester is primarily engaged in disseminating information to the public, (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

[8] https://www.bmj.com/content/378/bmj.o1731/rr-1.
[9] *Id*.

disseminated quickly, and (3) the request for records specifically concerns identifiable operations or activities of the Federal Government. 21 C.F.R. §§ 20.44(a)(2), (c)(1)-(3).

FDA does not challenge the first and third criteria and argues only that "Plaintiffs had not established an urgency to inform the public," (Dkt. 27-2 ¶ 27) claiming that "public debate about an FDA-regulated product does not create an 'urgency' within the meaning of the expedited processing standard." (Dkt. 27 at 16.) Here, the difference is that FDA has, unlike with other products, been actively promoting this product, and the government has mandated it and granted its manufacturer financial immunity for injuries they cause.

If independent scientists must wait 23 years, it is not that "a particular value [] will be lost," it is the entire value. By then, our country may have faced another pandemic and government response, which will no doubt be informed by its response to Covid, complete with new emergency use biologic products, immunity to liability, government promotion, and mandates. Absent timely production, the data cannot be used to learn from recent mistakes to improve next time.

FDA should not be allowed to haphazardly slow-leak documents, while arguing PHMPT has not had a bombshell discovery, to support slow leaking documents here. In any event, there is much the public has learned from the incomplete release in PHMPT 1, including these examples:

- A post-authorization adverse event report revealed for the first time that Pfizer had to "take[] a multiple actions [sic] to help alleviate the large increase of adverse event reports." These steps included "onboard[ing] approximately 600 additional full-time employees" with "more [] joining each month with an expected total of more than 1,800 additional resources by the end of June 2021."[10]

- The public learned for the first time that, in approximately the first 70 days following use of this product, there were 42,806 case reports containing 158,893 adverse events, including 1,223 deaths. Also disclosed for the first time were the system organ classes that contained the greatest number of events, including nervous system disorders (25,957), musculoskeletal and connective tissue disorders

[10] https://phmpt.org/pfizers-documents/ (type "reissue_5.3.6" in search bar, then download the document).

(17,283), gastrointestinal disorders (14,096), and skin and subcutaneous tissue disorders (8,476).[11]

- Independent scientists have also discovered that there are over 300 missing subject IDs in the trial data, including 111 missing IDs at one trial site, that are not explained by the documents produced to date and that have not been explained by FDA despite inquiry by the scientists.[12]

The completion of the BLA for Comirnaty is desperately needed by these independent reviewers so that they can conduct their own analyses and try to replicate those conducted by Pfizer and FDA. As one example, there is conflicting information about the number of deaths in Pfizer's clinical trial. In FDA's Summary Basis for Regulatory Action, it disclosed 38 deaths, with 21 in the vaccinated group and 17 in the placebo group.[13] In Pfizer's published study, it disclosed 34 deaths, 20 in the vaccinated group and 14 in the placebo group.[14] As one of the documents produced to date reveals,[15] the details of the deaths are expected to be explained in another Pfizer report which, despite a request to FDA months ago, it has yet to produce.

Researchers also want to compare a specific document related to waning immunity from FDA's files with a similar file released by Health Canada. To date, this has not been released in PHMPT 1, despite being a simple PDF file. Consequently, the comparison cannot be undertaken and it cannot yet be verified when Pfizer or FDA had evidence that the vaccine's efficacy waned.

Although FDA claims its website contains "the most relevant and current information about the COVID-19 vaccines," this has been demonstrably untrue in the past. (Dkt. 27 at 15). By way of just one example, FDA's website makes no mention of the data from Pfizer's trial showing

---

[11] *Id.* at 7.

[12] *See* https://openvaet.substack.com/p/pfizerbiontech-c4591001-trial-the. Without complete datasets, many independent scientists, researchers, and doctors are for now reporting their findings on Substack.

[13] *See* https://www.fda.gov/media/151733/download.

[14] *See* https://www.nejm.org/doi/full/10.1056/NEJMoa2110345.

[15] *See* https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf ("Full details and outputs regarding deaths, SAEs, safety-related participant withdrawals, and other significant AEs for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.4.").

that efficacy was variable over time and declined significantly following an early peak. An internal Pfizer report released by Health Canada indicates that, while these results were available to Pfizer as of April 2021,[16] they were not publicly disclosed until July 2021 in a Pfizer preprint.[17] During that crucial time period, public health officials and agencies, including FDA, were nonetheless relentlessly promoting the shots as stopping infection and transmission. Incredibly, even after the July 2021 preprint made waning immunity undeniable, both Pfizer and public health officials continued to claim the vaccines prevented infection and transmission.[18] This reinforces just how important it is for the public to have **full and timely** access to both Pfizer and Moderna Covid-19 vaccine data instead of relying on FDA pronouncements.

Finally, FDA claims to "agree[] that the COVID-19 pandemic and its associated vaccines are of paramount importance." (Dkt. 27 at 17.) FDA certainly agreed when it moved mountains to review the emergency use authorizations, to review the license applications, to grant authorization, to grant approval, and to promote the vaccines. However, FDA plainly does not "agree" when it comes to releasing the licensure data in its possession to the public in a timely manner. That, it seems, is not of paramount importance to FDA nor will it be unless ordered by this Court.

II. FDA'S PROPOSED RATE UNDERMINES FOIA AND ITS OWN REGULATION

FDA cites to *Colbert* which recognized that "Courts have broad discretion to determine a reasonable processing rate for a FOIA request" and that "[w]hen determining the rate at which a federal agency must respond to FOIA requests, courts often give deference to the agency's release

[16] https://clinical-information.canada.ca/ci-rc-vu.pdf?file=m5/53-clin-stud-rep/535-rep-effic-safety-stud/covid19/5351-stud-rep-contr/red-c4591001/red-c4591001-report-body-2.pdf&id=252736 at 102, 120.

[17] Stephen J. Thomas et al., *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, MedRxiv (July 28, 2021), https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.

[18] *See, e.g.*, https://www.cbsnews.com/news/transcript-dr-anthony-fauci-face-the-nation-05-16-2021/ (Fauci: "When you get vaccinated, …you contribute to the community health by preventing the spread of the virus … you become a dead end to the virus."). In fact, as late as October 2021, Pfizer claimed that "[m]aximizing the proportion of the population that is vaccinated is critically important to help reduce rates of infection, decrease transmission, prevent the emergence of new variants of concern…." https://www.fda.gov/media/153409/download#page=16.

policies." *Colbert v. FDA*, No. 16-1790, 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018). Here, the agency's release policy is "immediately available for public disclosure." 21 C.F.R. § 601.51(e).

Additionally, the FOIA backlog complained of is of FDA's own making, not that of the Court. The solution is to stop chronically underfunding its FOIA office. Congress made billions of dollars available to FDA to address Covid-19 and an appropriate portion should have been devoted to transparency and accountability to those providing these funds: the public. In any event, unless or until Congress changes the requirements of FOIA, FDA is not excused from them.

In this case there is extraordinary cause for concern. As noted, FDA, unlike with any other product, has been promoting this product before it was even licensed. (Dkt. 24 at 10.) As FDA is run by humans, not machines, it must be assumed this clouded its judgment. It would indeed cause cognitive dissonance, at the least, to admit that a product it wildly promoted turned out to be ineffective or caused serious harm. In fact, two of FDA's chief vaccine scientists left under protest because of its compromised and conflicted approach to the authorization of Covid vaccines.[19]

Instead of working with PHMPT in good faith, FDA stonewalled it. Critically, even after the court-ordered a production rate, FDA refused to create a priority list that would make production most effective, and instead has been producing in a manner that makes interim review nearly impossible. Indeed, on April 6, 2022, PHMPT requested the following documents be prioritized:

- Any periodic safety reports submitted by the sponsor to FDA, possibly referred to as SMSRs (See FDA-CBER-2021-5683-0000054 at 6);

- 5.3.5 Reports of Efficacy and Safety Studies;

[19] *See* https://www.nytimes.com/2021/08/31/us/politics/fda-vaccine-regulators-booster-shots.html and https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02046-8/fulltext?rss=yes.

> - 5.3.6 Reports of Postmarketing Experience (anything within this folder except the postmarketing report already produced starting at FDA-CBER-2021-5683-0000054); and
>
> - All records referenced in "License Action Recommendation Documents for Submissions and FDA Communication" at pages 9-17 of the Supplemental Index produced on Dec. 21, 2022, attached for convenience.

The following day, counsel for FDA responded as follows:

> FDA is generally willing to work with requesters to prioritize certain responsive materials as part of broader discussions about production schedules, when it is feasible to do so. Unfortunately, however, in the circumstances presented here it is not feasible for FDA to accommodate PHMPT's requests for prioritization.
>
> As you know, FDA is faced with an unprecedented processing schedule in this case. In order to keep up with the extraordinary speed required of the agency, FDA must retain sole discretion as to the order in which it will process the documents. Nothing in the court order permits PHMPT to dictate priority to the agency, and we are unable to accommodate this or any future similar request in this case.

It was thus disingenuous for FDA to claim that "CBER always stands willing to discuss ways to provide Plaintiffs with the information of greatest importance to them while also respecting the agency's limited resources." (Dkt. 27 at 27-28.) As is clear, FDA has unfortunately not sought to work with PHMPT and its resources were not "limited" when these products were being pushed out to America; they are limited only now when America wants full disclosure as to that process.

Bringing to a head Plaintiffs' most critical concern is FDA's admission that it does not know the current health status of the de Garay's daughter. (Dkt. 27 at 16.) Shouldn't the agency care? This case alone makes it plain FDA could not possibly have done a proper review of the clinical trial data and independent eyes are critically needed. Instead, the agency callously disregards her "health status" and makes an irrelevant and self-serving statement that it "is

currently in the process of producing COVID-19 vaccine-related records to the de Garays in another FOIA suit." (*Id*.) That FOIA request, however, is limited to email communications from 7 individuals within FDA that reference the de Garays' daughter and will not provide data from Pfizer about the trial she was involved in. Further, the de Garays are not due to receive all of those documents until near the end of this year.

CONCLUSION

Just as FDA did what it took to get the Covid-19 vaccines authorized, approved, promoted, distributed, and administered, it must do what it takes to release the complete data concerning those vaccines to the American public. Waiting over 23 years to do so completely undermines FOIA and FDA's claim of transparency. Plaintiffs therefore respectfully ask the Court to order FDA to produce all documents responsive to the Pfizer 12-15 request on or before October 15, 2023 and all documents responsive to the Moderna request on or before April 15, 2025.

Dated: April 12, 2023

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
745 Fifth Avenue, Suite 500
New York, New York 10151
Tel: (212) 532-1091
Fax: (646) 417-5967
Aaron@sirillp.com
Ebrehm@sirillp.com

Walker D. Moller, TX Bar No. 24092851
1005 Congress Ave., Suite 925-C36
Austin, TX 78701
Tel: (512) 265-5622
Wmoller@sirillp.com

John C. Sullivan, TX Bar No. 24083920
SL LAW PLLC
610 Uptown Boulevard, Suite 2000
Cedar Hill, TX 75104
John.sullivan@the-sl-lawfirm.com
Tel: (469) 523-1351
Fax: (469) 613-0891

Attorneys for Plaintiffs