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

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY and PATRICK AND STEPHANIE DE GARAY, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:22-cv-915-P

INITIAL JOINT STATUS REPORT

Plaintiffs Public Health and Medical Professionals for Transparency ("PHMPT") and Patrick and Stephanie de Garay, and Defendant United States Food and Drug Administration ("FDA") submit the following joint status report pursuant to this Court's Order dated February 7, 2023 (the "Order"). *See* Doc. 21.

1. This case involves Plaintiffs' Freedom of Information Act ("FOIA") requests to FDA which sought expedited processing for: (1) "[a]ll data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Events Reporting System ['VAERS']"; and (2) "[a]ll data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R § 601.51(e), with the exception of [public VAERS reports.]"

2. Since filing the initial Joint Scheduling Report on January 27, 2023, the parties have continued to confer and hereby update the Court as to the status of negotiations:

a. **FDA's position**: This is the parties' first joint status report. As explained in the Joint Scheduling Report, *see* Doc. 20, FDA agreed to make efforts to prepare materials for Plaintiffs to assist the parties' future discussions regarding the scope of Plaintiffs' FOIA requests and potential production schedules. On February 6, 2023, Defendant provided Plaintiffs with a comprehensive index of listings and page counts for Moderna's complete Biologic License Application ("BLA") for Spikevax, comprised of Moderna's original BLA and the subsequent amendments leading up to licensure for the vaccine. Defendant estimates that the complete BLA records for Spikevax total over 4 million pages. On February 8, 2023, Defendant provided Plaintiffs with a similar comprehensive index for Pfizer-BioNTech's complete supplemental BLA ("sBLA") for the ages 12-to-15 indication for the Comirnaty vaccine, comprised of the original sBLA and subsequent amendments leading up to approval for the indication. Defendant estimates that the complete sBLA records total nearly 0.5 million pages. On the afternoon of February 17, 2023 (the day this filing was due), Plaintiffs emailed Defendant, stating that they propose a production rate of 55,000 pages per month. The parties have not engaged in substantive negotiations about potential production timelines or the portions of BLA/sBLA records of greatest priority to Plaintiffs. Given the size and complexity of Plaintiffs' requests and the BLA and sBLA records (many of which may be responsive to Plaintiffs' FOIA requests), and the fact that Defendant would like to provide a proposal for a production rate to Plaintiffs, Defendant believes further review and discussion of the provided BLA/sBLA materials is important and that the parties should make a good-faith effort to negotiate a production schedule amongst themselves in the first instance. Moreover, Plaintiffs' Complaint requests that production in this case begin after the completion of production in another FOIA case in this Court. *See* Doc. 20 at 5 (describing *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022

WL 90237 (N.D. Tex. Jan. 6, 2022) ("*PHMPT 1*")). The next joint status report in *PHMPT 1* is due on March 24, 2023. Defendant respectfully requests time to continue discussions, to include providing Plaintiffs with a proposal for a production rate, and thus proposes filing a second joint status report about the status of negotiations on March 31, 2023, at which time the parties will have the benefit of the status update in *PHMPT 1*.

b. **Plaintiffs' position**: Plaintiffs' and Defendant's counsel have had four meet and confers and have exchanged numerous emails over the past three months.

Scope of the request: Plaintiffs have informed Defendants, after receipt and review of the indices for Moderna's BLA and Pfizer's supplemental BLA, that they are not willing to waive any documents that are responsive to the request. Until all the documents are produced, our clients cannot do a proper analysis, as noted in declarations by independent scientists in *PHMPT 1*.[1]

Timing and rate of production: Plaintiffs proposed in its October 11, 2022 complaint that FDA continue to produce the requested Moderna biologic product file ("BPF") and the Pfizer 12-15 YO BPF at the rate of 55,000 pages a month starting after the production in *PHMPT 1* ended. That proposal, however, was based on two incorrect assumptions. First, based on agency representations, Plaintiffs thought the production in *PHMPT 1* was a month or two away from completion at the time of filing. Second, it assumed there were going to be around 450,000 pages in the Moderna BPF, similar to what it understood was the page count in the Pfizer BPF (16 years and older), and far less than 450,000 pages in the 12 to 15-year-old Pfizer BPF.

[1] As one example, and as published in BMJ, numerous scientists are awaiting a key analysis dataset known as ADSL (Subject-Level Analysis Data) that has not yet been produced. Pfizer's own Analysis Data Reviewer Guide states that, "This [ADSL] dataset supported the creation of all other analysis datasets" and that "ADSL.sas must be run first before any other ADaM datasets; all other programs are depending on ADSL output." https://www.bmj.com/content/378/bmj.o1731/rr-1. Without this file, the document described above, and all other missing documents, PHMPT cannot conduct the necessary analyses. As Peter Doshi and Linda Wastila said: "This means that replicating even the most basic safety and efficacy analyses that Pfizer presented in its reports is still not directly possible." *Id*.

After this action was filed, Plaintiffs began to inquire with FDA's counsel as to when the production in *PHMPT 1* would end. However, the agency will not disclose – in either this action or in *PHMPT 1* –when the production in *PHMPT 1* will end. Plaintiffs therefore explained that they could not wait for some unknown date for the production in this matter to begin. Troublingly, it is now plain that there are far more pages than we and the Court were led to believe in *PHMPT 1*. The FDA repeatedly indicated there were approximately 400,000-450,000 pages,[2] and the Court

[2] The FDA, in PHMPT 1, made numerous representations to PHMPT and to the Court concerning the volume of responsive documents. These representations include (and reference the Dkt. numbers from PHMPT 1):

1. November 5, 2021 (Dkt. 18): "FDA has conducted an initial assessment of the number of records responsive to Plaintiff's FOIA request and has determined that **more than 329,000 page**s of documentary records, **plus other files…**"
2. November 15, 2021 (Dkt. 20): "Plaintiff takes issue with the amount of time it will take to process **329,000 pages** at a rate of 500 pages per month…"
3. December 6, 2021 (Dkt. 22): "FDA determined that the original Comirnaty BLA requested by Plaintiff comprises **more than 329,000 pages** of records. **In addition to those 329,000 pages, the original Comirnaty BLA includes data files** in a format similar to a spreadsheet for which a page count cannot readily be determined. FDA assessed that **Sections 5.2 and 5.3 comprise more than 321,000 pages of records** (plus additional data files) …"
4. December 6, 2021 (Dkt. 23): "ALFOI … determined that **the original Comirnaty BLA includes over 329,000 pages of records** for which pages could feasibly be counted. In addition to those 329,000 pages, the original Comirnaty BLA includes **additional data files in a format similar to a spreadsheet for which a page count cannot readily be generated. There are 126 of these data files in Section 5 of the original Comirnaty BLA alone,** and **there may be more** in other sections. For example, if BLA supplements, amendments and product correspondence are included, **the scope of Plaintiff's Request could expand by approximately 39,000 pages beyond FDA's initial estimate**. Similarly, if the investigational new drug applications were included, the scope of Plaintiff's Request would likely increase by tens of thousands of additional pages. FDA assessed that **Sections 5.2 and 5.3 comprise more than 321,000 pages of records (plus additional data file**s) …"
5. December 13, 2021 (Dkt. 29): "The processing schedule demanded by Plaintiff—that FDA process **approximately 329,000** record [sic] in a matter of mere *months* … Plaintiff's suggestion that FDA may meet its extraordinary demand to process **in excess of 300,000 pages of responsive documents** in a matter of mere months by "simply" re-assigning its personnel to is likewise misguided."
6. December 14, 2021 (Scheduling Conference): "The point is that where we're standing right now, at this very early juncture in this FOIA case, **the FDA simply has not had an adequate opportunity to get its arms around these 400,000 documents at issue here**. … At this moment, however, it just has not had sufficient time to get its arms around **the entire corpus of the 400,000 documents** at issue, especially to make a firm commitment as to how quickly it can get through that. … They're certainly entitled to the **full 400,000 documents** under the scope -- you know, under the FOIA statute, the FDA doesn't dispute that. But it is a choice that the plaintiffs are making to ask -- I should clarify, **that's somewhere in the ballpark of 400,000, once we added in the two additional categories of documents** that I think plaintiffs are saying, if I understand them correctly, they want … FDA to expand its construction of its request to encompass. **That will bring in an additional several tens of thousands of documents and pushes that somewhere close to around 400,000. … It just can't be the case that you asked for 400,000 documents and get them overnight**, which is, essentially, what they are asking for."

In addition, PHMPT echoed this volume estimate multiple times and the agency did not object to or correct those representations. *See, e.g.*, Dkt. Nos. 26, 31, 44, and the December 14, 2021.

said as much at the December 14, 2021 PHMPT 1 conference,[3] but we have received over 751,987 pages to date and there is apparently far more.

Again, Plaintiffs require production of the materials from *PHMPT 1* immediately in order to conduct crucial analysis. Until that material is provided in full, scientists cannot properly analyze the data therein. For example, the available data reflects there were 20 deaths among those receiving the vaccine and 14 among those receiving the placebo,[4] but until all the data is received, this cannot be confirmed. Similarly, Plaintiffs require the materials from this case immediately and, thus, Plaintiffs requested that the agency agree to begin producing documents at the rate of 55,000 pages per month beginning in two months.

Immediate need for the documents: There is an acute need for transparency concerning these products. For one, there are obvious efficacy issues with these products, and after the FDA has widely and voraciously promoted these products, including on its website[5] and promotional videos,[6] it is now conflicted from admitting it may have been mistaken. By promoting these shots, it has hopelessly conflicted itself from later admitting these products have serious issues, including with efficacy. There are now numerous datasets evidencing negative efficacy of these products. A recent study of approximately 50,000 workers in the Cleveland Clinic health care system shows, very clearly, that with each dose of COVID-19 vaccine, one's risk of contracting SARS-CoV-2 increases steadily.[7]

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[3] "…[Y]ou can even see this in tort litigation, 400,000 documents in modern-day litigation is really not a lot … Certainly in the litigation context, 400,000 documents just isn't a lot of documents in this day and age."

[4] *See* https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf.

[5] *See* https://web.archive.org/web/20230216052947/https://www.fda.gov/.

[6] *See* https://youtu.be/5kL9PIyru1w.

[7] Nabin K. Shrestha, *et al., Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine*, Medrxiv (Dec. 19, 2022), https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf?utm_source=substack&utm_medium=email.

With regard to the Pfizer documents submitted to license the vaccine for 12- to 15-year-olds, Plaintiffs Stephanie and Patrick de Garay's daughter is reason alone to demand transparency. Maddie de Garay was one of only 1,131 children in the Pfizer Covid-19 vaccine clinical trial for this age group. She was entirely healthy before entering the trial but, after her second shot, immediately required emergency medical attention and developed a cascade of medical issues that left her in a wheelchair and dependent upon a feeding tube to this day. Yet, Pfizer reported her reaction to FDA as "functional abdominal pain." Despite providing all of Maddie's medical records to the FDA, and numerous follow-ups with them including from undersigned counsel,[8] the FDA's only response was to tell her parents to file a VAERS report.[9] The de Garay family and PHMPT therefore believe it is a public health imperative that the clinical trial documents submitted by Pfizer to the FDA for this age group be released forthwith.

There are similar acute reasons for transparency regarding Moderna's data. Over the last year and a half, the over 20 studies at the core of CDC's claims these products are safe relied upon data collected in the CDC's v-safe safety system. This is its premier Covid-19 vaccine safety system that included 10 million people who completed weekly smartphone-based surveys during the six weeks after each dose of Covid-19 vaccine and then at 3-, 6-, and 12-months post-vaccine enabling the agency to "rapidly" study the safety of Covid-19 vaccines. Yet, in those studies, CDC only released the rate of Americans who reported needing medical care during the first week after receiving the vaccine even though it was collecting this information beyond the first week. After

[8] *See* https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-1-Oct.-22-2022-Ltr-to-Fed.-Health-Agencies-a4c120ce47dcfe008aa6d9ee38b682e4.pdf; https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-2-10-25-2021-VRBPAC-Letter_FINAL-3ba813862ca35aaea42a9c5dcf2480a0.pdf; https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-3-Jan-3-2022-Dr.-Peter-Mark-Letter_2022_01_03-41fe80ff1853909f2e9b5e329a55934e.pdf.

[9] https://www.sirillp.com/wp-content/uploads/2022/03/Paul-Richards-email-response_2022_02_26_Redacted-33b881e4534f7fc2af8e5872c01984ea.pdf.

a year-and-a-half legal battle to get this data, it was finally obtained and showed that 7.7% of those getting Covid-19 vaccines reported seeking medical care following vaccination, and these people disproportionately reported receiving the Moderna vaccine.

The fact that this medical product may cause harm is not surprising. What is deeply concerning is that the reality of harm reported from this product was hidden for over a year and a half while the public was provided only the first week of data which gave, at best, a distorted view. The data needs to be evaluated by neutral scientists who have never promoted these products to the American people, such that careers and reputation would be shattered by now admitting the opposite. This is the precise reason Plaintiffs now invoke their rights to obtain these documents in a timely manner.

Plaintiffs' proposal: The rate of 55,000 per month was proposed when it was understood that production for *PHMPT 1* was close to being completed. It was also proposed with the understanding that there would be a similar 450,000-page production for Moderna and a far smaller production for the 12- to 15-year-old Pfizer trial. Given that the end date for *PHMPT 1* is likely far away, and that FDA is saying there are likely millions of pages in the Moderna trial and 0.5 million pages in the Pfizer 12- to 15-year-old trial, Plaintiffs respectfully request that the Court order a production rate that is no less than 55,000 pages per month and that production in this matter begin on April 17, 2023.[10] Alternatively, Plaintiffs' request that the Court order Plaintiffs to file their opening brief as to the timing for producing responsive records by March 8, 2023, FDA to file its opposition by March 22, 2023, and Plaintiffs to file their reply by March 29, 2023.

Respectfully submitted,

[10] As FDA has previously explained: "If the parties are unable to agree upon a schedule, courts typically enter a processing schedule after considering arguments for each party's proposed schedule that were presented in a status report or at a scheduling conference." (Dkt. 20 in PHMPT 1).

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