

**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.

[illegible]

Civil Action No. 4:21-cv-01058-P

**APPENDIX IN SUPPORT OF DEFENDANT’S MOTION TO ALTER OR AMEND
JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 59(e)**

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Dated: January 3, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2025, I electronically filed this document with the Clerk of the Court for the United States District Court for the Northern District of Texas by using the CM/ECF system. Counsel in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

/s/ Andrew F. Freidah
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL
PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

Civil Action No. 4:21-cv-01058-P

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

DECLARATION OF SUZANN BURK

I, Suzann Burk, hereby declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management (“DDOM”), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research (“CBER” or the “Center”), United States Food and Drug Administration (“FDA”), in Silver Spring, Maryland.

2. A summary of my work experience and current job responsibilities is included in paragraph 2 of my declaration in this matter dated December 6, 2021. Burk December 2021 Decl., ECF No. 23, Ex. A.

3. DDOM is currently composed of the Access Litigation and Freedom of Information Branch (“ALFOI”), the Congressional and Oversight Branch, the Electronic Disclosure Branch, and two newly established Special Disclosure Units (“Units”) that report to a recently appointed Deputy Division Director. ALFOI consists of one branch chief and ten full time branch staff who handle the day-to-day work involved in the document disclosure duties. Three of those staff members are new employees who began working in ALFOI within the last two months. A

summary of ALFOI's responsibilities is included in paragraph 5 of my December 6, 2021 declaration. The newly created Units are primarily responsible for providing disclosure support where needed across DDOM. Currently, two ALFOI staff and all Unit staff are focused primarily on the related PHMPT II matter referenced below.

4. The statements contained in this declaration are based on my personal knowledge, as well as official FDA records and information available to me in my official capacity.

5. The purpose of this declaration is to explain the basis for the FDA's motion to alter or amend, pursuant to Federal Rule of Civil Procedure 59(e), the Court's December 6, 2024 Order requiring FDA to "produce the responsive [emergency use authorization ("EUA")] file on or before June 30, 2025," for Pfizer-BioNTech's COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older ("Pfizer's original EUA vaccine authorization"). ECF No. 101 at 9 ("December 6, 2024 Order"). Specifically, this declaration describes: (a) ALFOI's updated process for handling FOIA requests; (b) ALFOI's unprecedented workload obligations necessitating an alteration or amendment of the deadline; and (c) the status of ALFOI's search, pursuant to the December 6, 2024 Order, for the responsive EUA file.

6. As explained below, ALFOI has been working at full capacity to satisfy unprecedented productions ordered by this Court in the present matter, *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 4:21-1058-MTP ("PHMPT I"), and *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 4:22-cv-0915-MTP ("PHMPT II"), as well as other essential FOIA obligations. Collectively, this Court's prior Orders in PHMPT I and PHMPT II have required ALFOI to process at least an average of 55,000 pages per month from March 2022 to June 2023; 90,000 to 110,000 pages per month from July 2023 to November 2023; and, starting in December 2023, at least 180,000 pages per month until June

2025. See Order, at 1, PHMPT I, ECF No. 56, Feb. 2, 2022; Order, at 1-2, PHMPT II, ECF No. 38, June 12, 2023. Due to the number of estimated pages left to produce in PHMPT II, however, ALFOI will need to produce an average of more than 230,000 pages per month to meet the Court's June 30, 2025 production deadline in that case. Now, the Court's December 6, 2024 Order adds, at a minimum, 589,600 pages to ALFOI's processing obligations through June 30, 2025. These substantial productions have been ordered alongside a backdrop of other increased workload obligations, including an increase in FOIA requests and FOIA litigation stemming, in large part, from requests related to FDA's work pertaining to the COVID-19 pandemic.

7. ALFOI has already had to triage its limited resources in order to comply with this Court's unprecedented production Orders while responding to other FOIA requesters. An alteration or amendment of the June 2025 deadline in this Court's December 6, 2024 Order, staying the deadline until ALFOI completes production in PHMPT II, will help ensure that: (a) ALFOI can comply with the PHMPT II production Order; (b) ALFOI can process the FOIA requests pending ahead of Plaintiff's Request, including other requests seeking records related to the COVID-19 vaccines – which means conducting searches for and identifying responsive records and then conducting a careful, line-by-line, word-by-word review of any responsive records, as required by the legal obligations detailed more fully below; and (c) ALFOI can search for the responsive EUA file and then conduct a careful, line-by-line, word-by-word review of the responsive records, as required by the legal obligations detailed more fully below.

ALFOI'S UPDATED PROCESS FOR HANDLING FOIA REQUESTS

8. FOIA requests for Center-maintained records are forwarded to ALFOI from the Division of Headquarters Freedom of Information in the Office of Disclosure, Information, Governance and Accessibility within FDA's Office of Management and Enterprise Services.

ALFOI places FOIA requests for Center-maintained records in one or more of six queues¹ of pending requests, based on the volume, complexity, or subject matter of the requested records. The six queues are:

- A. Fast Track: Requests in the Fast Track can be answered with readily available documents that are expected to require little to no redaction. Requests are placed in this track usually because they seek records that previously were reviewed and redacted (typically in response to a previous records request) or information that is publicly available (often from records that were reviewed, redacted, and placed on FDA's website). Typically, staff processing time is estimated to be less than four hours.
- B. Simple Track: Requests in the Simple Track require minimal processing time, estimated to take between 4 to 16 hours.
- C. Complex Track: The Complex Track includes requests that require more processing time than the Fast Track or Simple Track, i.e., estimated processing time of more than 16 hours. These requests usually require extensive time to locate, review, or redact the records and often involve voluminous records.
- D. Inspection Records Track: Requests in the Inspection Records Track seek records related to Center-led inspections. This track includes both simple, estimated

¹ ALFOI created the Inspection Records Track to process inspection-related requests more efficiently. Moreover, ALFOI previously had an "Influenza Track" that contained requests seeking records related to pandemic influenza, influenza vaccines, other flu-related topics. Because no requests were pending in the Influenza Track as of February 29, 2024, ALFOI eliminated the Influenza Track. In addition, requests that have been granted "expedited processing" by the Division of Freedom of Information are not placed in the tracks listed in this paragraph. Instead, those requests are handled separately and processed as soon as practicable on a first-in-first-out basis, based on the date of receipt. *See* 21 C.F.R. § 20.44(f).

processing time of less than 16 hours, and complex, estimated processing time of more than 16 hours, sub-queues.

E. Adverse Event Track: Requests in the Adverse Event Track seek records related to adverse event line listings and event reports. This track includes both simple, estimated processing time of less than 16 hours, and complex, estimated processing time of more than 16 hours, sub-queues.

F. 510(k) Track: This track includes requests seeking records related to pre-market notifications submitted by manufacturers under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360(k)) prior to commercial distribution of devices regulated by the Center.

9. Requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis (that is, the first request received and placed in the Simple Track will generally be assigned to a reviewer before the second request in the Simple Track). The speed at which a request is ultimately processed in relation to other requests in different queues (and even other requests in the same queue) can be affected by many variables, for example: the scope of the request; the speed at which a requester responds to inquiries from reviewing staff; and whether a request was initially routed to a different FDA component before it was determined that any responsive records would be housed within the Center. Moreover, some queues move faster than other queues, so the number of requests ahead of a particular request in one queue may not reflect whether it will be processed before a particular request in a different queue. Thus, a request at the front of the Complex Track might still be processed after a request with multiple requests ahead of it in the Simple Track.

10. When a request is assigned to a reviewer for processing, the reviewer must determine which locations are likely to have responsive records, which could entail searching for and collecting potentially responsive records from various file locations, including hard copy and electronic filing systems. In addition, a reviewer may need to contact Center personnel and direct them to search their individual files. Records available only in hard copy are scanned into electronic files. After the reviewer collects potentially responsive records, the reviewer conducts an initial review to determine which of the collected records are, in fact, responsive to the request. Next, the reviewer conducts a line-by-line, word-by-word disclosure review of the responsive records to determine which, if any, FOIA exemptions apply, and then electronically redacts the material, as appropriate. ALFOI's review may (and often does) require research to evaluate whether certain information falls within a FOIA exemption. For example, an ALFOI reviewer may research whether certain information has been made public and thus is no longer "confidential."

11. ALFOI may consult with FDA's Office of the Chief Counsel to resolve questions on complex or novel disclosure issues. In recent years, this has become an increasingly necessary step, as FOIA requests received by the Center have increased in complexity and scope. ALFOI may also consult with the submitter of requested records, particularly where required by its regulations. See 21 C.F.R. § 20.61(e) (outlining pre-disclosure notification process for certain records, to include review time by the submitter). After consultation or notification, as appropriate, the reviewer conducts a quality-control check to ensure that the responsive records have been properly prepared for public disclosure and, finally, prepares copies of the responsive records for delivery to the requester. Throughout the process, the ALFOI branch chief, Deputy Division Director, or I may provide substantive input regarding the scope of the record searches and whether the records, or portions thereof, may be disclosed.

12. Additionally, if a record contains information belonging to other federal agencies, FDA will send the record to the relevant federal agencies for consultation. These consultations can occur more than once in the review process and inform FDA's determination about the applicability of any FOIA exemption.

13. After the necessary review and internal and external consultations, records may be transmitted to FDA's Office of the Chief Counsel and the Department of Health and Human Services' Office of the General Counsel for legal defensibility review. Once that legal review is completed, a senior reviewer in ALFOI conducts a quality-control review to ensure that the responsive records have been properly prepared for public disclosure.

14. The same process set forth in paragraphs 9-13 for FOIA requests is followed with respect to records required to be produced in response to discovery requests, third-party subpoenas, and court orders in FOIA cases. However, when a pending FOIA request becomes the subject of litigation, the typical "first-in, first-out" process may be affected. For example, a court order (like those in *PHMPT I* and *PHMPT II*) may require ALFOI to process a request on a specific timeline, effectively mandating that a requester "jump" the queue. A court may also order the parties to confer and attempt to reach agreement on a production schedule. In the absence of a court order or a filed agreement between the parties on a production schedule, FOIA requests that are the subject of litigation remain in their original position in their assigned Track(s) and are not removed from the FOIA queue(s). Thus, if a FOIA request that was the subject of litigation came to the front of its queue (through the typical first-in, first-out process), ALFOI would not skip over the request because it was in litigation but, instead, would handle the request under the typical first-in, first-out process.

ALFOI'S UNPRECEDENTED WORKLOAD OBLIGATIONS

15. Prior to this Court's first production orders in *PHMPT I*, see ECF No. 35, Jan. 6, 2022; ECF. No. 56, Feb. 2, 2022 (modifying Jan. 2022 Order in part), ALFOI consisted of nine regular staff and one branch chief. With this staff, ALFOI was able to keep its FOIA queues relatively stable. The following table illustrates the total number of FOIA requests received by ALFOI from fiscal years 2015 to 2018 (ranging from 255 to 343 FOIA requests) and the number of FOIA requests pending at the end of each fiscal year (ranging from 39 to 54 FOIA requests). During this time, ALFOI's litigation workload was limited or non-existent in any given year.

ALFOI's FOIA Workload Summary - Fiscal Years 2015 to 2018

Fiscal Year	Total Requests Received	Pending Requests, End of FY	Total FOIA Litigation Cases Filed in FY
2015	255	39	0
2016	343	49	1
2017	266	47	0
2018	291	54	0

16. In fiscal year 2019, the number and complexity of FOIA requests received by the Center began to increase. As shown in the following table, by fiscal year 2021, the Center began to receive annual requests exceeding 500: 509 requests in fiscal year 2021 and 633 requests in fiscal year 2022. In fiscal year 2023, although the number of FOIA requests declined, the number of total requests that ALFOI was able to close also declined, and the number of pending requests increased. The increase in pending FOIA requests from the end of fiscal year 2019 to the end of fiscal year 2023 was exacerbated by requests for records related to the COVID-19 pandemic. Moreover, in fiscal year 2020, FOIA litigation demanding ALFOI's attention also began to add significantly to its workload.

ALFOI's FOIA Workload Summary - Fiscal Years 2019 to 2023

Fiscal Year	Total Requests Received	Total Requests Closed	Pending Requests, End of FY	Total FOIA Suits Filed
2019	391	361	83 pending	3
2020	399	280	197 pending	6
2021	509	326	380 pending	5
2022	633	471	532 pending	8
2023	487	336	679 pending	10

17. The total number of active litigations in a fiscal year may be higher because work on a litigation case may span more than one fiscal year. As of December 20, 2024, ALFOI is involved in twenty open litigation cases (including this one). Two of these cases involve FOIA requests that are in the Complex Track like the Request at issue in this litigation and that were submitted to the agency before Plaintiff's Request in this case. See *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1905-JDB (D.D.C.) (FOIA Request No. 20-7162 received on October 7, 2020) and *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1761-CJN (D.D.C.) (FOIA Request No. 20-7656 received on October 26, 2020). And ten others involve requests in the Complex Track received after Plaintiff's requests in *PHMPT II* and before the December 6, 2024 Order. See *Informed Consent Action Network v. FDA*, Civ. A. No. 23-0219-RBW (D.D.C.) (FOIA Request No. 22-4855 received on July 5, 2022); *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1906-CRC (D.D.C.) (FOIA Request Nos. 21-1209 and 21-1210 received on February 19, 2021, and FOIA Request No. 23-9452 received on October 25, 2023); *Children's Health Defense v. FDA*, Civ. A. No. 23-0220-RDM (D.D.C.) (FOIA Request No. 22-5587 received on August 2, 2022); *Children's Health Defense v. FDA*, Civ. A. No. 23-2316-LLA (D.D.C.) (FOIA Request No. 22-6494 received on September 9, 2022); *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378-RC (D.D.C.) (FOIA Request No. 23-1020 received on February 6, 2023); *Children's Health Defense v. CDC*, Civ. A. No. 23-0431-TNM (D.D.C.)

(Center for Disease Control FOIA Request No. 22-2105 consult received by FDA on August 2, 2023); *Informed Consent Action Network v. FDA*, Civ. A. No. 23-3675-JMC (D.D.C.) (FOIA Request No. 23-7590 received on September 1, 2023); *Informed Consent Action Network v. FDA*, Civ. A. No. 23-3282-ABJ (D.D.C.) (FOIA Request Nos. 23-9354 and 23-9370 received on October 23, 2023 and October 24, 2023); *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1555-RCL (D.D.C.) (FOIA Request No. 23-11544 received on December 29, 2023); and *John Solomon v. Dep't of Health & Hum. Servs.*, Civ. A. No. 24-0572-RBW (D.D.C.) (FOIA Request No. 24-54 received on January 3, 2024).

18. As of December 31, 2024, there are 844 pending FOIA requests.

19. Managing the FOIA backlog has required the dedication of substantial resources in light of this Court's unprecedented production orders in *PHMPT I* and *PHMPT II*. As of January 2, 2025, the Plaintiffs in *PHMPT I* and *PHMPT II* have collectively received approximately 4.5 million pages of records related to COVID-19 vaccines with at least 1.2 million pages of records still to be processed in *PHMPT II*.

20. To comply with this Court's first production Orders in this case for an average processing rate of 55,000 pages per month, see ECF Nos. 35, 56, which far exceeded FOIA processing rates typically ordered by courts, DDOM and ALFOI implemented sweeping organizational and work process changes, including, among other things, expanding ALFOI's staff by hiring contractors and additional full-time employees ("FTEs"), reorganizing staff, and diverting resources from processing other FOIA matters. Between February 2, 2022 and November 1, 2023, among other things, we assigned nine FTEs and hired approximately 9.5 (nine full-time and one part-time) contractors primarily to focus on processing records for the *PHMPT I* litigation, leaving a small team of six FTEs to assume primary responsibilities for all other FOIA requests.

The Center estimates that the total cost of contractors alone for processing records in PHMPT I has been approximately \$3.5 million.

21. While ALFOI was marshaling its resources to comply with the PHMPT I production order, FDA was sued again in PHMPT II, and this Court's production Order in that case required:

- A. From July 2023 to November 2023, monthly production rates ranging from 35,000 pages to 55,000 pages per month, concurrent with the 55,000 pages per month already being processed in PHMPT I;
- B. Starting in December 2023, at least 180,000 pages produced per month in PHMPT II; and
- C. All the Pfizer 12-15 records (estimated at nearly 500,000 pages) to be produced by January 2, 2024 in PHMPT II, and all the Moderna records (estimated at over 4 million pages) to be produced by June 30, 2025 in PHMPT II. Meeting these deadlines actually requires ALFOI to produce, on average, more than 230,000 pages per month.

22. Because of PHMPT II and an increase in FOIA litigation, the Branch once again reallocated its staff, leaving only a handful of staff working on all non-PHMPT FOIA requests. The Center brought on board six new employees between June-December 2023, five new employees between January-May 2024, and three new employees between October-December 2024—all of whom are currently being trained. Of the fourteen new employees, twelve are part of the Units (which are currently processing responsive records in PHMPT II), and two have been assigned to process FOIA requests unrelated to the PHMPT II litigation. In response to PHMPT I and PHMPT II, DDOM undertook immediate and aggressive efforts to hire staff and contractors.

and continues to maximize efforts to train additional staff and contractors, reassign staff as available to assist in review of some records, seek funding, and reorganize its resources in an attempt to effectuate production at a pace that is, to our knowledge, many orders of magnitude greater than anything any agency has ever encountered in a FOIA order.

23. ALFOI and DDOM have also been engaged in conversations with the Center's Director and Office of Management as well as FDA's Office of the Commissioner regarding the estimated resources needed to meet its court-ordered and essential obligations. The Center continues to carefully consider the number of employees/contractors needed for these productions, especially given the extremely high costs to the agency. Efforts to identify the availability of resources—particularly this quantity of resources during a time of budgetary uncertainty—are time-intensive and on-going.

24. Even if the Center is awarded additional resources, receiving funds and hiring are merely the first steps in a labor-intensive process needed to train new employees and new contractors so they can fully contribute to ALFOI's disclosure work. ALFOI cannot take shortcuts when hiring and training new employees. The process of advertising, recruiting, interviewing, and administrative onboarding new employees alone takes several months (assuming a qualified candidate is found). Then, after new personnel are onboarded, it takes approximately two years for them to be fully trained so they can fully contribute to ALFOI's disclosure efforts. In the meantime, more senior employees monitor new employees/contractors to ensure they perform straightforward tasks accurately. As they develop, new employees/contractors are asked to engage in more complex tasks, and current employees continue to provide oversight so that these tasks, which often require more guidance, are performed accurately. Given this necessary process, while new employees/contractors are in training, they slow, at least initially, the efficiency of current ALFOI

staff, because staff must balance the need to onboard and train new personnel against the need to timely and accurately process outstanding requests. Thus, although the Center's recent hiring and continued training efforts represent the agency's good-faith investment to comply with its court-ordered production mandates and address the existing backlog of FOIA requests, its resources remain limited by the lengthy ramp-up period for new employees/contractors.

25. Since the *PHMPT II* Order was issued on June 12, 2023, the Center, in consultation with the Office of the Chief Counsel, has reviewed every pending FOIA request that is the subject of litigation to determine whether the agency should request that the case be stayed to enable help ensure the Center to satisfy is able to satisfy its production mandates in *PHMPT I* and *PHMPT II*. In doing so, the agency considers, among other things, the legal/procedural posture of the case, whether the parties filed an agreed-upon production schedule, and the extent to which the request *will continue* to require Center FOIA resources. Among other things, the agency considers cases to be ill-suited candidates for a request for a stay where a production schedule had been filed with a court and production is nearly complete, where responsive records overlap partially or completely with court-ordered productions in other cases, where a request could be narrowed to eliminate Center-maintained records, or where the parties were in the midst of summary judgment briefing. For example, the agency determined that one case was not an appropriate stay candidate because the Center had agreed to a production schedule in March 2023 (before the *PHMPT II* order issued), had already produced more than half of the responsive records, and had determined that all responsive records overlapped with records ordered to be produced in *PHMPT II*. See *Defending the Republic v. FDA*, No. 22-cv-1237 (N.D. Tex.). By contrast, the agency determined that cases involving complex requests in which substantial processing (searching, review, and/or redaction) and production had not begun, or that would substantially impede the Center's ability

to comply with the court-ordered productions in *PHMPT I* and *II*, were more appropriate stay candidates.

26. To date, FDA (or the U.S. Department of Health and Human Services) has filed motions for eighteen-month stays in thirteen FOIA cases, in addition to this one, seeking Center records. FDA's basis for seeking a stay in those cases was based on the extraordinary circumstances imposed by the production orders in *PHMPT I* and *II* as well as the growing number of FOIA requests and FOIA-related litigation being handled by the Center. A stay has been granted, in whole or in part, in each case in which the court issued a ruling on the motion. The current status of the thirteen cases is listed below.

A. Suit Withdrawn – *Informed Consent Action Network v. FDA*, Civ. A. No. 23-1508-CKK (D.D.C.) (case filed May 25, 2023) (plaintiff dismissed complaint without prejudice on October 2, 2023).

B. Motions to Stay – Granted

1. *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378-RC (D.D.C.) (case filed May 18, 2022; order entered on October 13, 2023, granting unopposed motion for eighteen-month stay).
2. *Children's Health Defense v. FDA*, Civ. A. No. 23-2316-LLA (D.D.C.) (case filed August 10, 2023; order entered on December 13, 2023, granting eighteen-month stay until further order of court, with status report in six months addressing need for further stay of proceedings; order entered on Dec. 23, 2024, extending stay until further order of the court based on a continued finding of exceptional circumstances and due diligence).

3. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-0219-RBW (D.D.C.) (case filed January 25, 2023; order entered on November 21, 2023, vacating all pending deadlines and setting conference in six months to discuss status; order entered on May 24, 2024, extending stay, with status conference in six months; order entered on Nov. 25, 2024, extending stay, with status conference in approximately seven months).
4. *Children's Health Defense v. FDA*, Civ. A. No. 23-0220-RDM (D.D.C.) (case filed January 26, 2023; order entered on January 12, 2024, granting stay of six months, with joint status report in six months; order entered on October 24, 2024, recognizing "the unusual and extraordinary demands placed on the FDA" and FDA's hiring and training efforts and concluding "all that the Court can do is require the most expeditious processing of the request at issue, consistent with reality," so that FDA should "begin processing the responsive documents no later than August 9, 2026").
5. *Children's Health Defense v. CDC*, Civ. A. No. 23-0431-TNM (D.D.C.) (case filed February 16, 2023; order entered on July 24, 2024, granting six-month stay on the Department of Health and Human Services' motion, with status conference in six months to determine whether stay should be extended).
6. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-3675-JMC (D.D.C.) (case filed February 20, 2024; order entered on September 4, 2024, granting stay of six months, with joint status report in six months).

7. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-3282-ABJ, ECF No. 20 (D.D.C. June 13, 2024) (Oct. 11, 2024 Order) (granting stay of six months until March 14, 2025, with joint status report due on March 14, 2025)
8. *John Solomon v. Dep't of Health & Hum. Servs.*, Civ. A. No. 24-0572-RBW, ECF No. 25 (D.D.C. Feb. 29, 2024) (Oct. 25, 2024 Order) (granting stay until June 26, 2026, with a status conference scheduled for July 8, 2025, to “apprise the Court of the status of this case.”).
9. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1761-CJN, ECF No. 18 (D.D.C.) (Nov. 20, 2024 Order) (granting stay for approximately eight months, until July 21, 2025 with a status report on or before July 23, 2025).

C. Motions to Stay – Pending

1. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1555-RCL, ECF No. 16 (D.D.C.) (case filed May 25, 2024; motion for stay filed September 25, 2024; order withholding final decision, staying case for 60 days, and ordering the parties to file a status report at 60 days issued on Nov. 19, 2024).
2. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1905-JDB, ECF No. 14 (D.D.C.), (case filed June 28, 2024; motion for stay filed Oct. 25, 2024)

3. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-1906-CRC, ECF No. 16 (D.D.C.), (case filed June 28, 2024; motion for stay filed Nov. 4, 2024)

27. Since January 2022, the Center has restructured and added three supervisory positions and thirteen staff level positions across DDOM (one supervisory position), ALFOI (one staff level position), and the newly formed Units. Two of the new supervisory positions head the Units, which consist of six staff positions each. A total of twelve staff have been onboarded to the Units, all of whom are relatively (or brand) new and are receiving training. To date, all Unit staff have less than 2 years of required training to work independently, i.e., without supervisory review and oversight, to fully contribute to ALFOI's disclosure efforts. Six staff have 6 months or less training. All Unit staff are assisting with specific portions of the PHMPT II production. Even if agency production in PHMPT II had concluded, and Unit staff were free to process the responsive EUA file pursuant to this Court's December 6, 2024 Order in this case, many likely would not have the appropriate training to do so and would require close supervision.

28. The Center continues to train its newest contractors and staff. The Center has been able to retain eight of the contractor positions after the contract term ended earlier this year. Although these continued training efforts underscore the seriousness with which the agency takes its commitment to meeting its unprecedented FOIA obligations, they also cannot change the Center's workload capacity overnight or its need for a stay in this case.

PROCESSING THE EMERGENCY USE AUTHORIZATION FILE FOR PFIZER'S ORIGINAL EUA VACCINE AUTHORIZATION

29. As explained in my October 16, 2024 declaration in support of FDA's motion for summary judgment, EUA records are tracked in an FDA database called Biologics Investigation and Related Applications Management System ("BIRAMS"), which assigns each EUA a

submission tracking number (called an “Investigational and Related Applications (IRA) number”). ECF 92, Ex. A, ¶¶ 34, 42 (“First Burk SJ Decl.”). The IRA number associated with Pfizer’s COVID-19 vaccine EUA file is 27034. *Id.* An initial estimate of Pfizer’s submissions in support of its request(s) for emergency use authorization is that they comprise approximately 589,600 pages through the date of authorization, December 11, 2020. ECF No. 99, Ex. A, ¶ 25 (“2d Burk SJ Decl.”).

30. ALFOI anticipates, however, that the final page count for the responsive EUA file could be higher as additional records may be included. *Id.* Estimating the full scope of records contained in the responsive EUA file will require reviewing Pfizer’s submissions to determine, which records, if any, are incorporated by reference into the EUA (*e.g.*, records from the Investigational New Drug application (“IND”), as applicable). ALFOI will need to further search CBERConnect to identify any FDA-generated records that are part of the responsive EUA file, including records incorporated by reference into the EUA file by those FDA-generated records, as applicable. *See* First Burk SJ Decl. ¶ 32 (describing the CBERConnect database).

31. Additionally, to process the responsive EUA file, ALFOI will need to re-engage with Pfizer to obtain its assistance, initially, in identifying sections of the responsive EUA file that do not contain any trade secret or confidential commercial information subject to FOIA Exemption 4. Just as during ALFOI’s processing of the 1.2 million pages of responsive records already in this litigation, knowing which records Pfizer believes do not contain information protected by FOIA Exemption 4 will enable ALFOI to streamline its disclosure review. Although ALFOI will still need to review these records for other types of information protected by the FOIA exemptions (most notably, Exemption 6, which protects the privacy interests of clinical participants), the process is ultimately aided by Pfizer’s initial assistance. This is a dynamic process, of course, as

ALFOI will need to further consult with Pfizer for those records that Pfizer indicates likely, or do, have trade secret or confidential commercial information to inform the agency's analysis and ultimate decision of what to redact prior to disclosure.

32. To date, Plaintiff has received more than 1.2 million pages of records responsive to its Request. Yet, as of November 15, 2024, Plaintiff's FOIA Request is behind 135 earlier submitted FOIA requests that are still pending in the Complex Track, including two requests in litigation where the Center has sought a stay of production pending the conclusion of production in PHMPT II.

33. Plaintiff's FOIA Request is in the Complex Track because it is expected to require more processing time than the types of FOIA requests in ALFOI's Simple Track, including more time to: conduct the requisite line-by-line and word-by-word review of the records to determine whether any of the information contained in them is exempt from disclosure under FOIA; redact exempt information in accordance with agency procedure; conduct a quality-control review of the redactions; and prepare the records for production by FDA. The records in the responsive EUA file will impose a similar burden. In light of these facts, ALFOI determined that a stay of this Court's December 6, 2024 Order for the EUA file is necessary to avoid jeopardizing its ability to meet the requirements of this Court's *PHMPT II* production Order.

34. ALFOI understands that Plaintiff wants to receive the remaining records responsive to its Request as quickly as possible, and ALFOI is committed to processing the responsive EUA file as ordered by this Court. But given the substantial effect that this Court's Orders in PHMPT I and PHMPT II have had on ALFOI's workload since January 2022, the significant likelihood that ALFOI will be unable to comply with the current production deadline in PHMPT II absent a stay, and the fairness to other FOIA requesters currently positioned ahead of Plaintiff's Request in the

Complex Track. ALFOI cannot concurrently process and produce the responsive EUA file as contemplated by the Court in its December 6, 2024 Order. ALFOI therefore is requesting an alteration or amendment of the December 6, 2024 Order, staying the production deadline until the conclusion of production in *PHMPT II*. This timing reflects FDA's most current, realistic assessment of the remaining records to be produced in *PHMPT II*, the equities among non-PHMPT FOIA requesters, and the bare minimum time needed to overcome the staffing and budgetary problems created by the unprecedented PHMPT production Orders that FDA has been facing. In the coming months, ALFOI will continue its extraordinary efforts to maximize its chances of satisfying the court-ordered production in *PHMPT II* so it can then process the remainder of Plaintiff's FOIA Request in this case (*i.e.*, the responsive EUA file).

* * *

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

Executed on January 2, 2025.

Suzann H. Burk - Digitally signed by Suzann H.
Burk-S
S Date: 2025.01.02 19:27:54 -05'00'

SUZANN BURK
Director
Division of Disclosure and Oversight Management
Office of Communication, Outreach and
Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE,

Plaintiff,

vs.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant.

Civil Action
No. 1: 23-220

Washington, DC
October 4, 2024

9:12 a.m.

TRANSCRIPT OF STATUS HEARING
BEFORE THE HONORABLE RANDOLPH D. MOSS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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P R O C E E D I N G S

THE COURTROOM DEPUTY: We are here on civil case number 23-220, *Children's Health Defense versus United States Food and Drug Administration*.

Counsel, please state your name for the record, starting with plaintiff's counsel.

MS. EVANS: Good morning, Your Honor. This is Risa Evans for Children's Health Defense. And my cocounsel.

MR. FLORES: Ray Flores for Children's Health Defense. Good morning, Your Honor.

THE COURT: Good morning.

MR. GEORGIEV-REMMEL: Good morning, Your Honor. Dimitar Georgiev-Rommel for the Food and Drug Administration. I am also joined on the phone by Elizabeth Bonomo. She is a law clerk at the FDA.

THE COURT: All right. Why don't we go ahead and start with you if you can give us any update on where things stand, both with respect to the PHMPT 2 litigation as well as the request in this case.

MR. GEORGIEV-REMMEL: Of course, Your Honor. The FDA continues to comply with the production order. It is making regular production in that case. My understanding is that to meet the June 2025 deadline, it needs to process 230,000 pages per month, which it is only required to process 180,000 per month. It is meeting those obligations.

1 In terms of this request, I have some updated
2 numbers, Your Honor. I am told that as of September 6, 2024
3 which is the latest update for which we have an update, the
4 request has moved two spaces. And it now is 301st in the
5 queue. That is an update from our August submission.
6 Moreover, I am told that FDA has now hired six new FTEs since
7 our report. Three of those, once trained, will be dedicated to
8 processing (inaudible) FOIA requests.

9 THE COURT: I'm sorry. Three will be dedicated to --

10 MR. GEORGIEV-REMMELE: These are the updates, Your
11 Honor, since our (Inaudible) --

12 Three will be dedicated generally to processing non
13 (inaudible) --

14 THE COURT: I have lost you.

15 MR. GEORGIEV-REMMELE: I didn't hear your question.

16 THE COURT: You are cutting in and out. So dedicated
17 to processing what?

18 MR. GEORGIEV-REMMELE: I apologize. Non-PHMPPT pages.

19 THE COURT: I see. Okay. All right. Anything more
20 from the plaintiffs?

21 MS. EVANS: Your Honor, I guess it is hard to sort of
22 know what the significance is of the new information without
23 additional information about, you know, how long it is going to
24 take for the new FTEs to be trained, et cetera, et cetera. So
25 I think that we are still in a situation where, you know, what

1 we last heard is that it was going to be at least 24 to 36
2 months until our FOIA request is reached. We are still in a
3 situation I think where the FDA's lack of diligence in
4 processing our request, in particular, and requests in the
5 complex queue in general is really still an issue. I don't
6 think that this sort of vitiates that. I think -- just a
7 couple of more points.

8 THE COURT: I'm sorry. Just on that point here, I
9 think that sort of kind of blanks reality here a little bit.
10 They have hired numerous additional people to do this. The
11 problem here is the Texas litigation. That is the problem.
12 There is a completely unreasonable demand being placed on the
13 FDA in the Texas litigation. And that is the problem here. I
14 mean, they have done their best. They have hired a number of
15 additional people. And so it is a little hard for me to know
16 what else I can do with the FDA. They don't have an unlimited
17 budget. I can't tell them to go hire a thousand people because
18 they don't have a budget to do that.

19 MS. EVANS: A couple of points, Your Honor. First, I
20 think it was clear from a number of the FDA's pleadings that
21 until now all of the new personnel that were hired were
22 channeled to the Texas litigation. And, in fact, up until this
23 latest report the number of personnel who were processing
24 requests that were not part of the Texas litigation was reduced
25 from 2022, not increased. It went down. It was six in 2022

1 and it was five up until this new information that just came
2 in. So for a couple of years while the backlog was growing,
3 nothing happened in terms of the processing of the non-PHMPT
4 requests. The second thing is that the -- you know, the FDA
5 has now I think 169 FOIA personnel. And, again, it seems that
6 there is this real bottleneck that has been created within
7 ALFOI specifically for the vaccine-related request that are
8 channeled to the complex queue. And the FDA is really the only
9 entity in a position to do anything about that. In terms of
10 the unfairness of the PHMPT orders, the FDA was the only entity
11 in a position to challenge those orders. Instead of doing
12 that, it is shifting the costs to all other FOIA requestors.

13 THE COURT: I am not sure it is fair to say they
14 didn't challenge it. I am confident they opposed those
15 requests.

16 Let me ask you -- I was actually wondering just about
17 that topic though. Why haven't you and all of the other FOIA
18 requestors gone down to Texas and either moved to intervene in
19 that case and at least filed an amicus brief in that case and
20 said, Judge, do you realize you are shutting down everyone else
21 in the country because of what you are doing here?

22 Why haven't you done that?

23 MS. EVANS: I don't think we have standing to do
24 that. That is a very interesting thought.

25 THE COURT: You can file an amicus brief letting the

1 judge down there know the consequences of what he is doing is
2 he is shutting down everyone else's FOIA requests in the
3 country.

4 MS. EVANS: Again, the burden on us as FOIA
5 requestors is to make a request that is well formulated, which
6 we did over two years ago. We also at the time sought
7 expedited processing. And although the FDA continues to deny
8 that there is any urgency for these records, again, it was very
9 clear -- Your Honor asked them after the last status conference
10 whether these records had been disclosed anywhere else. And
11 those are records that are specifically addressed to whether
12 any of the massive number of adverse events reported to VAERS
13 are actually causally linked to the COVID shots. It is the
14 only records that are out there about this.

15 The FDA and the CDC continue to rely on the
16 monitoring of VAERS that underlies our FOIA request. And yet
17 still this information has not been made public. And that is
18 very clear from the FDA's last filing.

19 So, you know, with the continued kind of promotion of
20 the shots and the continued statements about their safety and
21 efficacy, we, the American people -- we are sort of on behalf
22 of the American people saying, just show us the safety data.
23 And the 150 pages of records that are really most at issue in
24 this case, which have been sought by three other requestors --
25 and I think Your Honor is aware of that. This 150 pages of

1 records, I mean, would take to produce these -- the FDA didn't
2 actually answer the question in their pleading. But it would
3 probably take less than a half hour of processing time.

4 And another note just on that --

5 THE COURT: I am not sure that is true. I thought
6 they addressed it. I thought they said it would take them 30
7 days. There was something in there.

8 MS. EVANS: What they said is they would have to free
9 up approximately one month of staff time to process 150 pages
10 of records, because of how the requests are assigned to FOIA
11 personnel.

12 THE COURT: Right.

13 MS. EVANS: But it is very obvious, I mean, it can't
14 possibly take a full month of staff time. That is 40 hours --
15 160 hours to process 150 pages of records. I mean, that is
16 just not possible. You think about this speed with which they
17 are processing the PHMPT -- I did the math. It is in the
18 footnote of our pleading. It should take an hour at most of
19 actual time to process these records. So I am not sure -- I
20 don't really understand, except if there is something very,
21 very wrong with how the requests are processed there that it
22 could take a full month of staff time to process 150 pages of
23 records. It just doesn't make any sense.

24 And the other thing is we know that these records are
25 basically statistical analyses, which are not -- which don't

1 fall into any FOIA exemptions and cover emails. So at a very
2 minimum, I think producing these records, which have been
3 sought, like I said, by at least three other requestors
4 including a sitting US senator, ICAN in another state lawsuit
5 and a journalist, at least producing these records, would
6 certainly be within the realm of possibility, putting aside the
7 need for other searches, you know, just at a minimum these
8 records. But to make us wait for another two to three years
9 for records that are really going to be so stale by then, they
10 are just -- there is no value to them.

11 THE COURT: I agree completely with everything you
12 are saying. And I think the problem is that there is an
13 unreasonable request or demand on the FDA in the Texas
14 litigation, in which they have to comply with that on pain of
15 contempt. And there are other people who are in the queue.
16 And what is bothering me here is I am open to the notion of
17 saying, just produce it and do it. But when I am doing that, I
18 think what I am saying is someone else is not going to get
19 their records who is ahead of you in the queue. That is what
20 troubles me is why, you know, given the limited resources and
21 the unreasonable demands from the Texas litigation, why do you
22 get to jump the queue over the person whose records would
23 otherwise be processed right now?

24 MS. EVANS: Your Honor, a couple of things. First of
25 all, the FDA in a number of places in their pleadings sort of

1 make that argument, that somehow that requiring the FDA to
2 respond to us in a -- I won't say a timely fashion since it has
3 already been two years, but before another three years elapse,
4 that would be unfair. The unfairness doesn't come from
5 responding to us. The unfairness comes from how the queues
6 have been managed and how the FDA has addressed the situation.
7 It is not --

8 THE COURT: That is not -- I am not sure that is --
9 that gets to my point. I appreciate your concerns. And I
10 think they are entirely legitimate concerns. But I think we
11 all have to be sort of realistic about what is going on. The
12 FDA has hired additional people. And you say, well, they are
13 using more people to do the Texas litigation. That is so they
14 are not held in contempt of court down there that they are
15 doing that. It is not their choice. It is not they are
16 saying, well, all of the new people we are going to devote to
17 Texas. They are saying, we have to do that because the judge
18 has ordered us to do it down there. So they have limited
19 resources. There are other people who are in the queue. It
20 doesn't strike me as an incorrect argument for the FDA to make
21 or it doesn't seem to me that they are positioning themselves
22 in any way to simply say, we have got this unreasonable request
23 demanded on us in Texas. We have to comply on that with pain
24 of contempt. We can only obtain so many additional resources.
25 We have done everything we can. But with that, we have to

1 process things in order, because that is the only fair way to
2 do it.

3 MS. EVANS: I think that Open America and the other
4 cases and the FOIA statute itself recognize that when a party,
5 you know, is interested enough in records to put the effort
6 into litigation, that that means something. Otherwise, the
7 statute wouldn't require a quicker turnaround time on responses
8 to lawsuits when they are filed. I mean, I think that, you
9 know, the fact that a lawsuit has been filed, the fact --

10 THE COURT: Excuse me. Where in the statute does it
11 say there is a quicker turnaround time when you file a lawsuit?

12 MS. EVANS: I will have to look at that. I'm sorry.
13 I don't have the -- I think it is 30-day response time instead
14 of a 60-day response time for the defendant. I don't have the
15 citation in front of me, but I am happy to provide that to Your
16 Honor. And if I misspoke, I will let you know that as well,
17 but that is my understanding.

18 THE COURT: Okay.

19 MS. EVANS: We routinely in the lawsuits that we have
20 filed, we have agreed to extensions to 60 days. But I think
21 that the Open America, the case itself sort of talks about
22 that, particularly in the concurrence. And, again, we have
23 argued, you know, that the FDA does not -- I think it granted
24 one out of, you know, 300 requests for expedited processing in
25 the last year or something like that. It does not tend to

1 grant requests for expedited processing. But, again, I would
2 argue the Open America case made it very clear that Open
3 America stays are appropriate only when there is no urgency for
4 the records. And we have made a case for urgency from the
5 outset here. This is not something where we sort of sought
6 records on a casual basis and got tired of waiting and, you
7 know, filed a lawsuit. So I think that is another way this is
8 really different from Open America.

9 THE COURT: But still, what do I do though? I mean,
10 because I think what you are asking me to do means to say to
11 them, either push somebody else back in the queue or
12 potentially violate the order in Texas. Those are -- they are
13 hiring people already. So I am not sure what their other
14 options are.

15 MS. EVANS: Well, Your Honor, I guess what I would
16 suggest is that, you know, if the FDA adds the resources that
17 it would take to process our request and to move the expedited
18 processing queue along, then the other requestors in that queue
19 really get the benefit of our having litigated this. And so,
20 you know, so we move to the front of the queue, but the queue
21 actually starts moving instead of sort of sitting as a holding
22 tank.

23 THE COURT: I am not sure I understand that either.
24 I mean, the queue is moving at whatever rate it is moving at.
25 And only -- it would mean someone whose request would be

1 processed tomorrow is not going to be requested until a month
2 later, however long it takes to process your request and they
3 get pushed back by that period of time.

4 MS. EVANS: Well, I think if the Court ordered
5 production of the 150 pages of records, it would push requests
6 back about an hour. Again, because that is how much time it
7 will actually take to process the records. It just doesn't
8 take, you know, a month of staff time to review 150 pages of
9 statistical analysis to decide whether it is exempt or not. So
10 I think that that argument really just doesn't go anywhere.

11 And then, again, in terms of the other requests, you
12 know, I suspect that if the FDA is working to move the queue
13 along, part of the reason for that is the pressure from
14 litigators like ourselves and the few other plaintiffs who have
15 been seeking requests that have been languishing in that queue.
16 So I would submit in truth, you know, putting our requests at
17 the front of the queue where we have invested the effort to
18 really, you know --

19 THE COURT: But a bunch of my colleagues have issued
20 stays in cases where people have gone to the trouble of
21 litigating, so you would be bumping ahead of them because they
22 have got stays in place.

23 MS. EVANS: Well, we are two of those. Two of the
24 other cases are ours. And then another case I think is the
25 Informed Consent Action Network's case, which is also seeking

1 the EB mining records. They are a little bit ahead of us in
2 the queue. I am not sure who the last case is. We would be
3 sort of bumping ourselves in the queues, because several of
4 those are --

5 MR. GEORGIEV-REMMELE: Judge, may I respond briefly to
6 a couple of points from counsel.

7 THE COURT: Yes. But before you do, so I actually
8 had a question for you. If you could address the 150 pages and
9 how long it is going to take to process.

10 MR. GEORGIEV-REMMELE: Of course, Your Honor. We have
11 provided a written submission on that in our August report.
12 That is on pages 9 through 12. It is the Agency has determined
13 it would take about a month of staff time. It is not --

14 THE COURT: Why is that? Why isn't Ms. Evans correct
15 about that? How can it possibly take a month to review 150
16 pages, even assuming that there have to be two or three levels
17 of review of those pages. It does seem like a month of staff
18 time or 160 hours it is a little bit implausible to say that it
19 would take that much time to review 150 pages.

20 MS. EVANS: My understanding, Your Honor, is it is
21 not just looking at the documents. As you said, it might take
22 a couple of levels of review. But those are -- a lot of these
23 documents involve Excel spreadsheets. So it is not just 150
24 pages. There is data there that needs to be reviewed. There
25 are emails that need to be reviewed. The production needs to

1 be prepared so that it can be produced. So it is not just
2 looking at the documents. There are a number of steps that
3 need to happen, between identifying those documents, processing
4 them and actually producing them.

5 THE COURT: Is there anyone who is higher up in the
6 queue who has requested the same 150 pages? Ms. Evans said
7 there were three other requestors. Are any of those requestors
8 higher up in the queue, so if you processed that request it
9 would get Ms. Evans what she is looking for?

10 MR. GEORGIEV-REMEL: I believe so. Just looking at
11 our submission, I think that was the first question that we had
12 addressed in the overlap that the Court asked us last time.
13 That is on pages 3 through 5 in our written submission.

14 MS. EVANS: Your Honor, if I might, just to be a
15 little bit more specific, one of the litigations that is stayed
16 which is the ICAN, Informed Consent Action Network litigation
17 in this District, they are ahead of us in the queue. And that
18 is exactly what they are seeking is those 150 pages. The other
19 two requesters that I mentioned did not file suit. One was
20 Senator Johnson and other one was The Epoch Times. And neither
21 one of them, as far as I know, filed suit. And Senator Johnson
22 wasn't in any queue because he made the request through a
23 different channel. And The Epoch Times, you know, I think
24 because they -- the request was denied as ours was initially.
25 The FDA said, without having actually located the records that

1 they were all exempt from disclosure under the deliberative
2 process exemption. So they are not in the queue as far as I
3 know, unless they are in an administrative appeal queue.

4 THE COURT: So the Informed case, is that the one
5 that is in front of Judge Walton?

6 MS. EVANS: Correct.

7 MR. GEORGIEV-REMMELE: Yes.

8 THE COURT: Is the Informed Consent Action Network
9 involved in the Texas litigation?

10 MS. EVANS: Yes, they are. Well, no, not Informed
11 Consent Action Network is not, no. That is a different group.
12 It is Physicians for Public Health and Medical Transparency.
13 It is a different organization, I believe.

14 MR. FLORES: Same attorney, Your Honor, but a
15 different organization.

16 THE COURT: I'm sorry?

17 MR. FLORES: It is the same attorney, Your Honor,
18 just a different organization.

19 THE COURT: I see. I see. Okay. Thank you.

20 All right. Mr. Georgiev, you can continue.

21 MR. GEORGIEV-REMMELE: I just wanted to address one
22 point that my colleague on the other side made regarding taking
23 the time to litigate and that somehow pushes the FOIA request
24 ahead of ours. If that is the position that -- we disagree
25 with that, because that would reward requestors who are able to

1 obtain counsel, who are able to have the funds to obtain
2 counsel and to litigate to the detriment of other requestors
3 who might not be able to do so.

4 The way that the FDA is processing these requests is
5 on first in, first out basis. That is the most equitable way
6 of doing so. That is what Open America has said is the
7 appropriate way of doing the request, not whether a party is
8 represented or not.

9 THE COURT: So do you know where the Informed Consent
10 Network's request is in the queue, for the 150 pages?

11 MR. GEORGIEV-REMMELE: I do not. I can follow up.

12 THE COURT: Because the stay in that case ought
13 not -- consistent with what you are saying, the stay is of the
14 litigation. The stay is not of our obligation to process.

15 MR. GEORGIEV-REMMELE: Correct.

16 THE COURT: And so --

17 MR. GEORGIEV-REMMELE: Correct. Those people --

18 THE COURT: If they are higher up, maybe you are
19 going to get to those sooner and that is going to resolve the
20 issue on the 150 pages, at least.

21 MR. GEORGIEV-REMMELE: I will follow up with -- I will
22 find out and follow up with you, Judge.

23 THE COURT: Ms. Evans, did you want to say something
24 about that?

25 MS. EVANS: I just looked at the latest pleading in

1 that case which was filed in June and they are still -- they
2 were as of June somewhere in the 300s, I believe. So it is
3 still several years away from processing. It is not like they
4 are up close to the front of queue. I think their request was
5 filed about a month before ours was. So it is sooner, but not
6 meaningfully sooner.

7 THE COURT: And, Mr. Georgiev, come June of 2025 what
8 happens with respect to the Texas litigation? Is there another
9 tranche of documents that are materials that are going to have
10 to be reviewed and produced there or is the FDA done come June
11 of '25 with the Texas case?

12 MR. GEORGIEV-REMMEL: Honestly, Judge, I don't want
13 to try and predict what happens there. We thought after PHMPT
14 1 that the FDA was done. But then we got PHMPT 2. Certainly,
15 the FDA's hope is we will be done with that case and producing
16 in that case. And the resources that were dedicated to PHMPT 2
17 could be dedicated to clearing out the backlog. And that is
18 the anticipation from FDA. But who knows what the Court in
19 Texas does.

20 THE COURT: Where do the requests in the PHMPT case
21 stand in relation to the requests here, for example? So were
22 there multiple requests there? And were they all before the
23 Children's Health Defense request or were some of those after
24 that request?

25 MR. GEORGIEV-REMMEL: I am not sure I understand your

1 question, Your Honor.

2 THE COURT: So the FDA is responding in the Texas
3 litigation's request it received from PHMPT; correct?

4 MR. GEORGIEV-REMMELE: Yes.

5 THE COURT: And I assume that there are multiple
6 requests in this case or maybe there is just one request. I
7 don't know.

8 MR. GEORGIEV-REMMELE: The Court's indulgence.

9 THE COURT: I will tell you why I am asking the
10 question. Which is, if there are other requests that have been
11 made that are potentially subject to the litigation in Texas,
12 that came in after Children's Health Defense's request here, I
13 may well want to put an order on the books to make clear that.
14 FDA's next obligation is to respond to Children's Health
15 Defense request, because I have been deferential to the judge
16 in Texas, because he has an existing order in place. But if we
17 are lining up in making a queue here, I want my order in place
18 before his next one, if there is one coming, if it relates to
19 FOIA requests that came before whatever FOIA requests he -- I
20 don't want this to be a process that goes on forever down
21 there, where people keep just adding and adding to their
22 requests, even with requests that came in later so they are all
23 jumping the queue. And then all of the other judges in the
24 country are deferring to one judge in Texas who is doing this
25 out of a matter of comity. Because comity runs two ways. And

1 if that is what is going on, I want to make sure I have an
2 order on the list in place that that judge in Texas has to show
3 some comity too and says that that order comes before his
4 order -- next order of priorities. That is the reason for my
5 question.

6 MR. GEORGIEV-REMMELE: I understand your question.
7 No, Judge. I think I would need to go back and get authority
8 to articulate its position on what Your Honor thinks.

9 THE COURT: Okay. All right. I don't know enough
10 about what is going on in the litigation down there. But if it
11 was just one request that was a gigantic request that came in
12 years ago that is still being processed, that is one thing. If
13 it is a series of requests including ones that came in after
14 the request at issue here, that is a different thing.

15 Ms. Evans, do you know the answer to that question?

16 MS. EVANS: I do not, Your Honor.

17 THE COURT: Okay. Well, I have to say, I am still
18 somewhat at a loss as to what to do here, because I do think
19 the FDA is making good faith efforts. They are hiring
20 additional people. They are doing their best. They are under
21 some unreasonable demands. And I need to be cognizant of the
22 demands of others in the queue and need to make sure that I am
23 not treating anyone else unfairly in this process by allowing
24 someone to improperly jump the queue.

25 So I guess what I would like to do is two things:

1 One is, Mr. Georgiev, if you can get back to me and maybe if
2 you can just do this in a week and tell me how long literally
3 it is going to really take to process the 150 pages. I am
4 dubious that it really is 160 hours of time. And say, if we
5 were to process those pages, how long would it take? How long
6 would the review take? How long would the secondary review
7 take? I mean, Bates stamping and putting in the system isn't
8 going to take any time at all. So I would like to know with
9 more specificity and certainty how long it is going to take to
10 process those 150 pages. Because I am skeptical that it really
11 would require 160 hours of time to do that.

12 I would also like to know where the first requestor
13 is in the queue, the first requestor on those materials in the
14 queue, even if that requestor hasn't filed litigation. And
15 then I would like to know the answer to my question about what
16 is going on in the Texas litigation and whether -- where the
17 requests at issue in that litigation stack up as compared to
18 the requests in this case and whether there are other requests
19 in that case that -- or potentially in that case that came in
20 later where I need to make sure I am putting down a marker by
21 entering an order that these come next. And we are not waiting
22 forever for everything that gets filed in another jurisdiction
23 to get processed, even where those are requests that came in
24 months or years after the requests at issue in this case,
25 because that would be unfair.

1 MR. GEORGIEV-REMMEL: Understood, Your Honor. And I
2 think I heard you ask for a report within a week?

3 THE COURT: Is that possible?

4 MR. GEORGIEV-REMMEL: If you Your Honor orders us,
5 we'll make it possible.

6 THE COURT: No. I don't want to be -- I am trying
7 not to be unreasonable with you. I want to make sure you also
8 have time to accurately answer those questions. They don't
9 sound to me like terribly complicated questions. But if you
10 needed a little bit more time than a week, that would be okay
11 with me, so tell me what do you need to be --

12 MR. GEORGIEV-REMMEL: Two weeks. But if we have the
13 answer (inaudible) can we get two weeks as an order?

14 THE COURT: That is fine. So today is the 4th. So I
15 will order by the 18th you file a status report if you can
16 provide me with that information.

17 I would like to find some way to move forward with
18 the 150 pages, if there is a way to do that. I don't want to
19 do it in a way that is unfair to others that have been waiting
20 to have their requests processed. If it is just a few hours,
21 maybe that is not material anyway.

22 MR. GEORGIEV-REMMEL: Understood, Your Honor.

23 THE COURT: All right. Anything else?

24 MR. FLORES: One more thing to add, Your Honor, if we
25 do locate any information, case law that says those who file

1 suit have priority, may we submit that to the Court as well?

2 THE COURT: I would appreciate that if you did, yes.

3 MR. FLORES: Thank you.

4 THE COURT: All right. Anything else from you,

5 Mr. Flores or Ms. Evans?

6 MS. EVANS: No. Thank you, Your Honor.

7 THE COURT: All right. This is a very frustrating
8 circumstance for everybody involved and we have to do our best
9 with it. Thank you.

10 MR. FLORES: Thank you, Your Honor.

11 MS. EVANS: Thank you, Your Honor.

12 MR. GEORGIEV-REMMEL: Thank you, Judge.

13 (Proceedings concluded at 9:42 a.m.)

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C E R T I F I C A T E

I, Sherry Lindsay, Official Court Reporter, certify that the foregoing is a true and correct transcript of the remotely reported proceedings in the above-entitled matter.

PLEASE NOTE: This hearing occurred by videoconference and is therefore subject to the technological limitations of court reporting remotely.

Dated this 13th day of October, 2024.

A handwritten signature in black ink, appearing to read 'Sherry Lindsay', is written over a horizontal line.

Sherry Lindsay, RPR
Official Court Reporter