UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK, *Plaintiff*, v. FOOD AND DRUG ADMINISTRATION, et al. *Defendants*.	Civ. A. No. 25-825 (RDM)

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") in the Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland. I have been the Director of DDOM since June 24, 2018.

2. As the Director of DDOM, I have overall responsibility for the disclosure of records officially maintained by CBER, which is the FDA component that regulates biological products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular- and tissue-based products. 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. Prior to becoming the Director of DDOM, I worked within three of these DDOM areas. I was the Team Lead of the Electronic Disclosure Team for approximately

nine-and-a-half years. Before that, I was a member of the Congressional and Oversight Branch for two years and, before that, a member of ALFOI for four years.

3. ALFOI is primarily responsible for the review and disclosure of CBER-maintained records in response to Freedom of Information Act ("FOIA") requests and FOIA litigation. At times, ALFOI will also be responsible for other litigation-related document requests, such as responses to discovery requests and third-party subpoenas. In addition, ALFOI responds to consultation requests from other federal agencies and other FDA components that are processing FOIA requests for records that contain information related to CBER. Records in a consultation request need to be reviewed, redacted, and returned to the entity requesting the consult for production.

4. The newly created Units are primarily responsible for providing disclosure support where needed across DDOM. Currently, the Unit staff are focused mainly on the *PHMPT I* and *PHMPT II* matters described below.

5. I submit this declaration in support of Defendants' Motion for an Eighteen-Month Stay of Proceedings in the above-captioned case. 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.

6. The purpose of this declaration is to explain the basis for FDA's request for an eighteen-month stay, with a status report two weeks thereafter addressing the agency's ability to proceed with this case at that time. Specifically, this declaration describes CBER's disclosure staff's[1] general FOIA responsibilities and necessary work processes, current processes for

[1] For ease of reference, "CBER's disclosure staff" or "CBER's disclosure office" refers to "DDOM," "ALFOI," and "the Units," collectively.

handling FOIA requests, the status of Plaintiff Informed Consent Action Network's ("ICAN") FOIA request, and recent and unprecedented workload obligations necessitating the requested stay.

7. As explained below, CBER's disclosure staff has devoted substantial resources to satisfy the unprecedented production orders entered by the United States District Court for the Northern District of Texas in *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 21-1058 (MTP) (N.D. Tex.) ("*PHMPT I*") and *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 22-0915 (MTP) (N.D. Tex.) ("*PHMPT II*"). CBER maintains a number of queues for handling different categories of FOIA requests, based on anticipated processing time (*e.g.*, simple to complex) or record type (*e.g.*, inspection reports), processing each queue generally on a first-in, first-out basis, to provide an efficient and fair release process. "Jumping the queue" may happen, however, when a court imposes a different time frame, for example, by setting a deadline, or the parties agree on a processing schedule. As further explained below, *PHMPT I* and *PHMPT II* have imposed on FDA an extraordinary workload, still ongoing, that FDA could not have predicted, and FDA has been working to the best of its ability in responding to those orders. Later orders in *PHMPT I* and *PHMPT II* have increased the total number of pages to be produced in both cases by approximately sixty percent. These orders have jumped *PHMPT I* and *PHMPT II* to the front of the queue and necessarily delayed processing of all other requests.

8. Collectively, *PHMPT I* and *PHMPT II* required CBER's disclosure staff to produce at least 90,000 to 110,000 pages per month from July 2023 to November 2023. Then, in *PHMPT II*, after a brief ramp-up period, CBER's disclosure staff was ordered to produce at least 180,000 pages per month and complete production by June 30, 2025. To meet the court's deadline in *PHMPT II*, CBER's disclosure staff had to produce at times more than 230,000 pages per month.

As of June 2, 2025, CBER's disclosure staff has produced over 4.3 million pages in *PHMPT II* and 1.7 million pages in *PHMPT I.* These substantial productions have been ordered alongside a backdrop of other increased workload obligations, including an overall increase in FOIA requests and FOIA litigation over the past few years stemming, in large part, from requests related to FDA's work pertaining to the COVID-19 pandemic. As further explained below, CBER's disclosure staff took extraordinary measures, including the hiring of temporary contract staff, to meet these orders.

9. In *PHMPT I*, a dispute arose as to whether an emergency use authorization ("EUA") file fell within the scope of the FOIA request. On December 6, 2024, the court held that it did and ordered that the production be completed on or before June 30, 2025, which is the same production deadline entered in *PHMPT II*. Mem. Op. & Order, *PHMPT I*, Civ. A. No. 21-1058, (Dec. 6, 2024), ECF 101. On January 10, 2025, the court denied FDA's motion to alter the judgment to extend the production deadline. *Id.*, Op. & Order (Jan. 10, 2025), ECF 108. As a result, FDA has had to process approximately 600,000 additional pages of records by the June 30, 2025, deadline.

10. Pursuant to a follow-on order in *PHMPT II*, FDA also must produce two additional EUA files containing approximately 2.8 million additional pages of records, for a total increase in both cases of approximately 3.4 million pages.[2] These additional records, in turn, raise the number of pages collectively sought from approximately 5.7 million to 9.1 million, an increase of approximately 60 percent. CBER's disclosure office currently anticipates meeting the June 30, 2025, deadline in *PHMPT I.* On May 15, 2025, the Court ordered the additional records in *PHMPT*

[2] Am. Order, *PHMPT II*, ECF No. 52 (June 9, 2025) (entering negotiated schedule); Joint Status Report, *PHMPT II,* ECF No. 49 (May 14, 2025).

II to be produced by October 1, 2026, again at a minimum monthly rate of 180,000 pages per month.

11. CBER's disclosure office has had to triage its limited resources to comply with these unprecedented court-ordered productions while responding to other FOIA requesters. At the same time, CBER's disclosure office resources have also been increasingly devoted to lawsuits from plaintiffs represented by Siri & Glimstad ("Siri"), who are also plaintiffs' counsel in *PHMPT I* and *PHMPT II*. Indeed, Siri is counsel for plaintiffs in the vast majority of the current FOIA litigation related to records processed by CBER's disclosure office, and CBER's disclosure office has received hundreds of FOIA requests from 2019 to date from Siri or Siri-represented parties.

12. Additionally, a recent, unanticipated staff disruption affecting CBER's disclosure office heightens the need for a stay. On April 1, 2025, staff in several FDA divisions, including some within CBER's disclosure office, received reduction-in-force ("RIF") notices and were placed on administrative leave. In May 2025, FDA began the process of rescinding RIF notices for FOIA staff within CBER's disclosure office and reincorporating those who agreed to return to their respective offices. FDA continues to evaluate the cumulative impact of staff and contractor departures, a hiring freeze, and funding uncertainty on immediate operations, including CBER's processing of FOIA matters.

13. A stay of this case will help ensure that CBER's disclosure office can meet its *PHMPT* deadlines while continuing to process the FOIA requests pending ahead of Plaintiff's request, 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 then apply the same procedures to Plaintiff's request when it reaches the front of the queue.

FDA'S LEGAL OBLIGATIONS TO PROTECT CONFIDENTIAL INFORMATION

14. Many records that are responsive to FOIA requests received by CBER contain information that is exempt from disclosure. FOIA exempts several categories of information from its disclosure requirements, including trade secrets and confidential commercial or financial information obtained from a person (5 U.S.C. § 552(b)(4)); information covered by the deliberative process privilege, attorney work product privilege, or attorney-client privilege (5 U.S.C. § 552(b)(5)); and personnel, medical, and similar files if disclosure would result in a clearly unwarranted invasion of personal privacy (5 U.S.C. § 552(b)(6)).

15. Consistent with FOIA's exemptions, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the release of trade secret information to those other than Department of Health and Human Services employees, Congress, or the courts where relevant in cases brought under the FDCA (21 U.S.C. § 331(j)). The Trade Secrets Act prohibits the release of trade secret information unless otherwise authorized by law (18 U.S.C. § 1905). In addition, FDA regulations provide that information is unavailable for public disclosure if it is: a trade secret or commercial information that is privileged or confidential (21 C.F.R. § 20.61); or identifying information in medical or similar files that, if disclosed, would be a clearly unwarranted invasion of personal privacy (21 C.F.R. § 20.63). As specified by regulation, FDA is also authorized to withhold from public disclosure its intra- and inter-agency communications (21 C.F.R. § 20.62).

16. As a result, it is important for CBER's disclosure office to perform a careful line-by-line, word-by-word review of all responsive records before production, parsing the information that is protected from the information that is not.

CBER'S DISCLOSURE OFFICE'S PROCESS FOR HANDLING FOIA REQUESTS

17. FOIA requests for CBER-maintained records are forwarded to CBER's disclosure staff from the Division of Headquarters Freedom of Information, which is the centralized intake and administrative processing center for FDA FOIA, in the Office of Disclosure, Information, Governance and Accessibility within FDA's Office of Management and Enterprise Services. CBER's disclosure office places incoming FOIA requests for CBER-maintained records in one or more of six queues,[3] 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 four to sixteen 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

[3] CBER's disclosure office eliminated its "Influenza Track," which contained requests seeking records related to pandemic influenza, influenza vaccines, and other flu-related topics, because no requests were pending in that Track as of February 29, 2024. Requests that have been granted "expedited processing" by FDA's Division of Headquarters Freedom of Information are not placed in the tracks listed in paragraph 17. 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).

than sixteen hours. These requests usually require extensive time to locate, review, and/or redact the records and often involve voluminous records.

D. Inspection Records Track: Requests in the Inspection Records Track seek records related to CBER-led inspections. This track includes both simple (estimated processing time of less than sixteen hours); and complex (estimated processing time of more than sixteen hours).

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 sixteen hours) and complex (estimated processing time of more than sixteen hours) sub-queues.

F. 510(k) Track: This track includes requests seeking pre-market notification (21 U.S.C. § 510(k)) documents submitted by manufacturers prior to commercial distribution of devices regulated by CBER.

18. 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, including: 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 CBER. 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 could be processed after a request with multiple requests ahead of it in the Simple Track.

19. When a request is assigned to a reviewer for processing, the reviewer must search for and collect potentially responsive records from various file locations, including hard copy and electronic filing systems. In addition, a reviewer may need to contact CBER 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.

20. 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. CBER's review may (and often does) require research to evaluate whether certain information falls within a FOIA exemption. For example, a CBER disclosure office reviewer may research whether certain information has been made public and thus is no longer "confidential."

21. ALFOI may consult with FDA's Office of the Chief Counsel to resolve questions on complex or novel disclosure issues. Then, 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 may be disclosed.

22. Additionally, if a record contains information belonging to other federal agencies, FDA will send the record to the relevant 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.

23. 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 review. Once that legal review is completed, a senior reviewer in CBER's disclosure staff conducts a quality-control review to ensure that the responsive records have been properly prepared for public disclosure.

24. The same process set forth in paragraphs 19-23 for FOIA requests are 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 CBER's disclosure staff 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.

25. 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), CBER's disclosure staff 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.

CBER'S DISCLOSURE OFFICE'S UNPRECEDENTED WORKLOAD

26. Prior to the 2022 court-ordered production order in *PHMPT I*, ALFOI consisted of nine regular staff and one supervisor and there were no Units. 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 CBER's disclosure office 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 thirty-nine to fifty-four FOIA requests). During this time, CBER's FOIA litigation workload was limited or non-existent in any given year.

CBER Disclosure Office FOIA Workload Summary - Fiscal Years 2015 to 2018

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

27. Since fiscal year 2019, the number and complexity of FOIA requests received by CBER's disclosure office, with limited exception, increased. As shown in the following table, by fiscal year 2021, CBER's disclosure office began to receive annual requests exceeding 500: it received 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 CBER's disclosure office was able to close also declined while 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 2024 was due in large part to requests for records related to the COVID-19 pandemic. In fiscal year 2024, the number of FOIA requests appeared to be stabilizing and CBER's disclosure office was able to close more requests than in fiscal year 2023, but the number of pending requests increased.

CBER Disclosure Office FOIA Workload Summary - Fiscal Years 2019 to 2024

Fiscal Year	Total Requests Received	Total Requests Closed	Pending Requests, End of FY	Total FOIA Suits Filed
2019	391	361	83	3
2020	399	280	197	6
2021	509	326	380	5
2022	633	471	532	8
2023	487	336	679	10
2024	487	385	859[4]	11

28. Moreover, in fiscal year 2020, FOIA litigation also began to add significantly to the workload of CBER's disclosure office. More than ten new cases were filed in fiscal year 2024 seeking CBER records, an increase over fiscal year 2023, and another eleven were filed within the first five months of 2025. In total, from fiscal year 2019 to date, there have been more than fifty lawsuits filed seeking records maintained by CBER. As of June 5, 2025, CBER's disclosure office had approximately thirty open litigation cases.

29. Since 2019, Plaintiff has submitted more than 350 FOIA requests seeking CBER records, approximately 220 of which remain pending. ICAN is the plaintiff in approximately twenty-three of thirty-four of the open lawsuits seeking CBER records. Likewise, ICAN is the plaintiff in all eleven of the lawsuits filed to date in 2025, including this one.

30. Managing the FOIA backlog has required the dedication of substantial resources in light of the unprecedented court-ordered productions in *PHMPT I* and *PHMPT II*. *See* ¶¶ 7-11, *supra*.

31. The records in *PHMPT I* related to Pfizer-BioNTech's Comirnaty vaccine for COVID-19 approved for individuals 16 years of age and older consisted of over 1.2 million pages. The Northern District of Texas court ordered CBER's disclosure office to produce these records

[4] This number is fluid and includes, for example, pending appeals.

beginning in March 2022 at an unprecedented average rate of 55,000 pages per month. In consideration of the agency's motion to partially modify the scheduling order, the court imposed a graduated production schedule, which required CBER's disclosure office to produce 10,000 pages per month in March and April 2022; 80,000 pages per month in May, June, and July 2022; 70,000 pages in August 2022; and 55,000 pages per month thereafter. FDA completed those productions on November 1, 2023 (*PHMPT I*, ECF Nos. 67 and 75).

32. Given that the production rate ordered in *PHMPT I* far exceeded FOIA production rates typically ordered by courts, CBER's disclosure office 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. Among other efforts, the office initially assigned nine FTEs and hired approximately nine and a half (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. CBER estimates that the total cost of contractors alone for processing records in *PHMPT I* through the November 1, 2023, production date was approximately $3.5 million.

33. While CBER's disclosure office was marshaling its resources to comply with the *PHMPT I* production order, FDA was sued again in *PHMPT II*. In *PHMPT II*, the records at issue were in the Biological Product File(s) for Pfizer's approved 12-to-15-year-old indication for the Comirnaty vaccine for COVID-19 ("Pfizer 12-15 records") and Moderna's approved Spikevax

vaccine for COVID-19 ("Moderna records"), estimated to total over 4.5 million pages. On June 12, 2023, the court imposed[5] an even more burdensome monthly production schedule:

A. From July 2023 to November 2023, CBER was required to comply with monthly rates ranging from 35,000 pages to 55,000 pages per month. This production was concurrent with the 55,000 pages per month being produced in *PHMPT I*. The effort to comply with the production order contributed to the backlog in CBER's disclosure office.

B. Starting in December 2023, CBER was required to produce at least 180,000 pages per month in *PHMPT II*, although it has needed to produce, at times, more than 230,000 pages per month to meet the court's deadline.

C. Deadlines for completing the production in full compounded the burdens associated with the minimum monthly rates, which required the actual monthly productions to be even higher. All the Pfizer 12-15 records (estimated at nearly 500,000 pages) were produced by January 2, 2024, as required. All the Moderna BPF approval-related records (estimated at over 4 million pages) will be produced by June 30, 2025.

D. On May 15, 2025, the *PHMPT II* court ordered the roughly 2.8 million pages of responsive EUA files in *PHMPT II* to be produced no later than October 1, 2026, at the same minimum monthly rate of 180,000 pages per month. Orders, *PHMPT II*, ECF Nos. 49, 50.

34. Because of *PHMPT II* and an increase in FOIA litigation, CBER's disclosure office

[5] Order, *PHMPT II*, ECF No. 38 (June 12, 2023).

once again reallocated its staff, leaving only a handful of staff working on all non-*PHMPT II* FOIA requests. CBER's disclosure office also brought on board six new FTEs between June and December 2023. Then, in 2024, CBER's disclosure office brought on five more FTEs as well as additional contractors. Of the eleven new FTEs, nine were assigned as part of the Units, and two were assigned to process FOIA requests unrelated to the *PHMPT II* litigation. *See* ¶ 4, *supra.*

35. CBER undertook aggressive efforts to hire and 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. In total, since 2022, CBER's disclosure office added three supervisory positions and thirteen staff-level positions, more than doubling the size of the staff. Two of the supervisory positions were assigned to head the Units, which consist of six staff positions each. Since the beginning of 2025, three Unit staff and two senior ALFOI staff members have left the agency. Due to the current hiring freeze, which went into effect January 20, 2025, FDA is unable at this time to backfill these positions. Currently, six contractor positions remain. However, this contract is currently set to expire soon, and, though CBER is working diligently to obtain authorization to enter into a new contract for additional contractors, it is uncertain when that authorization will be granted. To date, the majority of Unit staff have less than two years of required training to work independently, i.e., without supervisory review and oversight, to fully contribute to CBER's disclosure efforts. All Unit staff are assisting with specific portions of the *PHMPT II* production.

36. Hiring new staff is merely a first step in the labor-intensive process needed to train employees so they can fully contribute to CBER's disclosure work. CBER's disclosure office

cannot take shortcuts when hiring and training new employees. The process of advertising, recruiting, interviewing, and administrative onboarding alone takes several months (assuming a qualified candidate is found). Then, after a new employee is onboarded, it typically takes approximately two years for an employee to be adequately trained so they can independently contribute to the office's disclosure efforts. In the meantime, more senior employees monitor new employees to ensure they perform their assigned tasks accurately. As they develop, new employees 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 are in training, they slow, at least initially, the efficiency of current staff, because staff must balance the need to onboard and train new hires against the need to timely and accurately process outstanding requests. Thus, although CBER's hiring and training efforts since 2022 represent the agency's good-faith investment to comply with its court-ordered production mandates and address the existing backlog of FOIA requests (including Plaintiff's requests in this case), its resources remain limited by the lengthy ramp-up period for new employees.

37. Since the *PHMPT II* order was issued, CBER, 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 case should be stayed to enable CBER to satisfy its production mandates in *PHMPT I* and *PHMPT II*. In doing so, the agency considered, among other factors, 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 CBER FOIA resources. Among other things, the agency considered cases to be ill-suited candidates for a request for a stay where a production schedule had been filed with a court and production was nearly complete, where

responsive records overlap partially or completely with court-ordered productions in other cases, where a request could be narrowed to eliminate CBER-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 CBER 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*, Civ. A. No. 22-1237 (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 were more appropriate stay candidates.

38. As of March 19, 2025, the date Plaintiff filed its complaint, FDA (or the U.S. Department of Health and Human Services) had filed motions for stays in thirteen FOIA cases seeking CBER records. A stay has been granted, in whole or in part, in each case in which the court issued a ruling on the motion,[6] as follows:

i. *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-cv-1378 (RC) (D.D.C. May 18, 2022), Min. Order, ECF No. 28 (Oct.13, 2023), (granting unopposed motion for eighteen-month stay), Motion to Extend Stay, ECF No. 48 (Apr. 25, 2025) (pending).

ii. *Children's Health Def. v. FDA*, Civ. A. No. 23-cv-2316 (LLA) (D.D.C.

[6] In *Informed Consent Action Network v. FDA*, Civ. A. No. 24-cv-1555 (RCL) (D.D.C. May 25, 2024), the court has not issued a final ruling on the stay motion. *See id.*, Order, ECF No. 13 (Sept. 25, 2024) (court withheld a final decision to stay under *Open America* or *Landis*, instead issuing an interim stay for sixty days). In *Informed Consent Action Network v. FDA*, Civ. A. No. 23-cv-1508 (CKK) (D.D.C. May 25, 2023), plaintiff dismissed its complaint before the court ruled on the stay motion. *See id.*, Order, ECF No. 16 (Oct. 3, 2023).

Aug. 10, 2023); Min. Order (Dec. 13, 2023) (granting eighteen-month stay until further order of court, with status report in six months addressing need for further stay of proceedings); Min. Order (July 18, 2024) (extending stay based on a continued finding of exceptional circumstances and due diligence); Min. Order (Dec. 23, 2024) (extending stay based on continued finding of exceptional circumstances and due diligence, with a status report due June 13, 2025).

iii. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-cv-0219 (RBW) (D.D.C. Jan. 25, 2023), Order, ECF 27 (Nov. 21, 2023)) (vacating all pending deadlines and setting conference in six months to discuss status); Order, ECF No. 29 (May 24, 2024) (extending stay, with status conference in six months); Min. Order (Nov. 25, 2024) (extending stay, with a status conference on July 7, 2025).

iv. *Children's Health Def. v. FDA*, Civ. A. No. 23-cv-0220 (RDM) (D.D.C. Jan. 26, 2023), Order, ECF No. 25 (Jan. 12, 2024) (granting stay of six months, with joint status report in six months); Min. Order (Oct. 24, 2024) (ordering FDA to begin processing responsive records no later than Aug. 9, 2026).

v. *Children's Health Def. v. CDC*, Civ. A. No. 23-cv-0431 (TNM) (D.D.C. Feb. 16, 2023), Order, ECF No. 28 (July 24, 2024) (granting six-month stay on the Department of Health and Human Services' motion); Min. Order (Jan. 24, 2025) (continuing the stay and ordering

the parties to submit a joint status report by April 25, 2025, and every 90 days thereafter).

vi. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-cv-3282 (ABJ) (D.D.C. Nov. 2, 2023), Order, ECF No. 23 (Oct. 11, 2024) (granting stay of six months, with joint status report in six months to determine whether stay should be extended); Mot. to Extend Stay, ECF No. 27 (March 14, 2025) (motion to extend stay for six months pending).

vii. *Informed Consent Action Network v. FDA*, Civ. A. No. 23-cv-3675 (JMC) (D.D.C. Dec. 10, 2023); Min Order (Sept. 4, 2024) (granting stay of six months, with joint status report on March 4, 2025); Order, ECF No. 25 (Apr. 10, 2025) (extending stay through October 10, 2025).

viii. *Solomon v. Dep't of Health & Hum. Servs.*, Civ. A. No. 24-cv-0572 (RBW) (D.D.C. Feb. 29, 2024); Order, ECF No. 25 (Oct. 25, 2024) (granting stay for approximately 20 months until June 26, 2026, with a status conference scheduled for July 8, 2025, to "apprise the Court of the status of this case").

ix. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-cv-1761 (CJN) (D.D.C. June 17, 2024); Order, ECF No. 18 (Nov. 20, 2024) (granting stay for eight months until July 21, 2025).

x. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-cv-1905 (JDB) (D.D.C. June 28, 2024); Order, ECF No. 17 (Feb. 4, 2025) (granting stay for six months until August 5, 2025).

xi. *Informed Consent Action Network v. FDA*, Civ. A. No. 24-cv-1906 (CRC) (D.D.C. June 28, 2024), Order, ECF No. 21 (Apr. 10, 2025) (granting stay for six months until October 10, 2025).

PLAINTIFF'S FOIA REQUEST

39. Plaintiff submitted its FOIA request, assigned FOIA Request No. 2024-965, on January 26, 2024, and CBER's FOIA office placed it in the Complex Track, where it is presently No. 482 (behind 481 earlier submitted requests).

40. ALFOI placed Plaintiff's FOIA request in the Complex Track because it is expected to require more than sixteen hours of processing time. This includes time to: search for and obtain responsive records, 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; redact exempt information in accordance with agency procedure; conduct a quality-control review of the redactions; and prepare the records for production by FDA. In light of these facts, CBER's disclosure office, after discussion with FDA counsel, determined that a stay in the present suit is necessary if CBER is to meet the requirements of the *PHMPT II* production order.

41. FDA understands Plaintiff's interest in receiving records responsive to its requests as quickly as possible, and CBER's disclosure office is committed to processing the FOIA requests as soon as it is in a position to do so. But given the substantial impact that *PHMPT I* and *PHMPT II* have had on CBER's disclosure office's workload, and the large volume of requests from Plaintiff and other requesters, CBER's disclosure office does not have the bandwidth at this time to concurrently process and produce records in response to the request at issue in this litigation. An eighteen-month stay is sought, at which time FDA will be in a better position to evaluate its progress in *PHMPT II* and as to when it might be in a position to respond to Plaintiff's FOIA

request. Eighteen months reflects FDA's most current, realistic assessment of the bare minimum time needed to overcome the staffing and budgetary problems created by the unprecedented production orders that FDA has been facing. In the coming months, CBER's disclosure office will continue its efforts to maximize its chances of satisfying the court-ordered production in *PHMPT II* so it can resume processing other outstanding FOIA requests, including Plaintiff's request at issue in this case and the other requests Plaintiff previously submitted.

42. Given the substantial continuing impact of *PHMPT I* and *PHMPT II* on CBER's resources despite significant office reorganization to accommodate the increased FOIA request and litigation workload, CBER's disclosure office does not have the capacity at this time to produce records in response to the request at issue in this litigation.

43. If a stay is granted in this litigation, Plaintiff's request would retain its place in the Complex Track. Although the majority of CBER's disclosure office's resources currently must be devoted to reviewing records to satisfy the *PHMPT II* order, ALFOI continues to process requests, as it is able, in its regular FOIA queues. Although the pace at which FOIA requests can be processed has been slowed substantially by production orders like those issued in *PHMPT I* and *PHMPT II*, ALFOI continues to assign and process FOIA requests generally on a first-in, first-out basis. Accordingly, if a stay is granted and the requests ahead of Plaintiff's requests in the Complex Track are processed before the stay ends, CBER's disclosure office would process Plaintiff's request when it reaches the front of the queue, and the court would be notified.

* * *

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

Executed on June 13, 2025.

Suzann H. Burk -S

Digitally signed by Suzann H. Burk -S
Date: 2025.06.13 08:28:56 -04'00'

Suzann Burk
Director
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