UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 23-0220 (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"), Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of records officially maintained by CBER, the center in FDA that regulates biological products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products (HCT/Ps). I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine-and-a-half years. Before that, I was a member of the Congressional and Oversight Branch in DDOM for two years and, before that, a member of the Access Litigation and Freedom of Information Branch ("ALFOI") in DDOM for four years.

3. DDOM is composed of the ALFOI, the Congressional and Oversight Branch, and the Electronic Disclosure Branch.

4. ALFOI is primarily responsible for the review and disclosure of CBER-maintained records in response to FOIA requests and FOIA litigation. ALFOI may also, at times, be responsible for other litigation-related document requests, such as responses to discovery requests and third-party subpoenas. ALFOI also 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. These records need to be reviewed, redacted, and returned to the entity requesting the consult for production.

5. The statements contained in this declaration are based upon 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 that this case be stayed for eighteen months, followed by a status update from the agency about its ability to proceed with the case at that time. Specifically, this declaration describes: 1) ALFOI's general FOIA responsibilities and necessary work processes; and 2) ALFOI's recent and unprecedented workload obligations.

7. As explained below, ALFOI is currently working at full capacity to satisfy unprecedented productions ordered by the United States District Court for the Northern District of Texas in *Pub. Health & Med. Pros. for Transparency* ("*PHMPT*") *v. FDA*, Civ. A. No. 21-1058 ("*PHMPT 1*") and *PHMPT v. FDA*, Civ. A. No. 22-0915 ("*PHMPT 2*"), as well as other essential FOIA obligations. Collectively, these cases require ALFOI to produce at least **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. These substantial productions have been ordered

alongside a backdrop of other increased workload obligations, including an increase in incoming FOIA requests and FOIA litigation stemming, in large part, from requests related to FDA's work pertaining to the COVID-19 pandemic. In recent years, ALFOI's resources have been increasingly devoted to lawsuits from plaintiffs represented by Siri & Glimstad ("Siri"), who are plaintiffs' counsel in *PHMPT 1* and *PHMPT 2*. Indeed, Siri is counsel for plaintiffs in the majority of the current FOIA litigation related to CBER records processed by ALFOI, and ALFOI has received hundreds of FOIA requests to date from Siri or Siri-represented parties.

8. ALFOI must immediately triage its limited resources in order to comply with these unprecedented court-ordered productions while responding to other FOIA requesters. A stay of this case will help ensure that ALFOI can conduct a careful, line-by-line review of any responsive records in this case and others, as required by the legal obligations detailed more fully below.

FDA'S LEGAL OBLIGATIONS TO PROTECT CONFIDENTIAL INFORMATION

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

10. 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, *inter alia*, that: (a) trade secret and privileged or confidential commercial information is unavailable for public disclosure; and (b) identifying information in medical or similar files (which, if disclosed, would be an unwarranted invasion of personal privacy) is unavailable for public disclosure. 21 C.F.R. §§ 20.61, 20.63.

11. As a result, it is important for ALFOI 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.

ALFOI'S PROCESS FOR HANDLING FOIA REQUESTS

12. FOIA requests for CBER-maintained records are forwarded to ALFOI from FDA's Division of Freedom of Information in the Office of the Executive Secretariat, Office of the Commissioner of Food and Drugs. ALFOI places each request in one or more of six queues of pending requests, based on the volume, complexity, and/or subject matter of the requested records. Requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis.

13. 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, s/he conducts an initial review to verify that the records are, in fact, responsive to the requests. 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 (i.e., is no longer "confidential").

14. 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 or I may provide substantive input regarding the search's scope and whether the records may be disclosed.

15. 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.

16. 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.

17. The same process set forth in paragraphs 13-15 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.

ALFOI'S UNPRECEDENTED WORKLOAD OBLIGATIONS

18. Prior to the 2022 court-ordered production order in *PHMPT 1*, 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[1]
2015	255	39	0
2016	343	49	1
2017	266	47	0
2018	291	54	0

19. In fiscal year 2019, the number and complexity of FOIA requests received by CBER began to increase. As shown in the following table, by fiscal year 2021, CBER began to receive annual requests exceeding 500: 509 requests in fiscal year 2021 and 633 requests in fiscal year 2022. This increase was exacerbated by requests for records related to the COVID-19 pandemic. Moreover, in fiscal year 2020, FOIA litigation cases also began to add significantly to ALFOI's workload.

[1] This reflects the fiscal year in which the complaint was first filed.

ALFOI's FOIA Workload Summary - Fiscal Years 2019 to 2022

Fiscal Year	Total Requests Received	Total Requests Closed	Pending Requests, End of FY	Total FOIA Litigation Cases Filed[2]
2019	391	361	83 pending	3
2020	399	280	197 pending	6
2021	509	326	380 pending	5
2022	633	471	532 pending	8

20. As of August 2, 2023, ALFOI has received 262 FOIA requests from Siri or a Siri-represented party—60 of which have been the subject of agency appeals, and 18 of which have been the subject of litigation.[3] Of these 262 FOIA requests, 142 remain pending.[4]

21. Although data for fiscal year 2023 is not yet complete, the data collected as of June 30, 2023, shows that ALFOI has received 369 new FOIA requests and that ten new FOIA lawsuits were filed involving CBER records. Currently, ALFOI has twelve active litigation cases, including this one. Moreover, the number of pending FOIA requests has increased (660 requests), while the number of closed FOIA requests in 2023 (242 requests) has decreased when compared to this point in the previous fiscal year.

22. Managing the FOIA backlog requires the dedication of substantial resources in light of the unprecedented court-ordered productions in *PHMPT 1* and *2*. In *PHMPT 1* and *PHMPT 2*, plaintiffs have collectively sought approximately **5.7 million** pages of records related to COVID-19 vaccines.

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[2] 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.

[3] Some of the FOIA requests are grouped with others in the same suit, and thus the number of suits the Branch is involved in is lower than the number of requests in litigation.

[4] This includes requests that have been appealed or are the subject of active litigation.

23. The records at issue in *PHMPT 1*, in which plaintiff is represented by Siri, constitute over 1.1 million pages related to Pfizer-BioNTech's Comirnaty vaccine for COVID-19 approved for individuals 16 years of age and older. The Northern District of Texas ordered ALFOI to produce the *PHMPT 1* records beginning in March 2022 at an unprecedented average rate of **55,000** pages per month.[5] FDA anticipates that the productions of *PHMPT 1* records will be completed by November 2023.[6]

24. Given that the production rate ordered in *PHMPT 1* far exceeded FOIA production rates typically ordered by courts, DDOM and ALFOI implemented sweeping organizational and work process changes, including, among other things, hiring contractors and additional full-time employees ("FTEs"), reorganizing staff, and diverting resources from processing other FOIA matters. Among other things, we assigned nine FTEs and hired approximately 9.5 (nine full-time and one part-time) contractors to primarily focus on processing records for the *PHMPT 1* litigation, leaving a small team of six FTEs to assume primary responsibilities for all other FOIA requests.

25. CBER estimates that the cost of contractors alone for processing records in *PHMPT 1* will total approximately $3.5 million through October 2023. This past spring, ALFOI received approval to hire six new FTEs, which will cost an estimated $1.8 million annually (in salary, benefits, and other employee-related expenses). These FTEs have only recently joined ALFOI and are currently being on-boarded and trained. Aggressive efforts to recruit and train contractors and new staff and implement other work process changes remain ongoing.

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[5] In consideration of the agency's motion to partially modify the scheduling order, the court imposed a graduated production schedule, which required ALFOI 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.

[6] *See PHMPT 1*, Civ. A. No. 21-1058, ECF No. 67 (N.D. Tex. Mar. 24, 2023).

26. While ALFOI was marshaling its resources to comply with the *PHMPT 1* production order, Siri-represented parties (including repeat plaintiff PHMPT) again sued FDA in *PHMPT 2*. In *PHMPT 2*, the records at issue are estimated to be over 4.5 million pages related to Pfizer's 12-to-15-year-old indication for the Comirnaty vaccine for COVID-19 ("Pfizer 12-15 records") and Moderna's Spikevax vaccine for COVID-19 ("Moderna records"). After substantial briefing and a hearing (*see PHMPT 2*, ECF Nos. 27 and 34), in which ALFOI emphasized its unprecedented workload and significant resource constraints amidst a growing FOIA backlog, the same court imposed an even more burdensome monthly production schedule:

a) From July 2023 to November 2023, ALFOI must comply with monthly rates ranging from **35,000** pages to **55,000** pages per month in *PHMPT 2*. This is **concurrent** with the **55,000** pages per month being produced in *PHMPT 1*.

b) Starting in December 2023, ALFOI must produce at least **180,000** pages per month in *PHMPT 2* (at that time, the productions in *PHMPT 1* should be complete).

c) Deadlines for producing the records in full compound the burdens associated with the minimum monthly rates, which may require the actual monthly productions to be even higher. The Pfizer 12-15 records (estimated at nearly **500,000** pages) must be produced in full by January 2, 2024. The Moderna records (estimated at over **4 million** pages) must be produced in full by June 30, 2025.

ALFOI is undertaking immediate and aggressive efforts to hire additional staff and contractors, 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.

27. The court's order in *PHMPT 2*, which provides a table of ALFOI's monthly obligations in *PHMPT 1* and *2* from July 2023 to June 2025, is attached to this declaration as Attachment A.

28. Since the issuance of the *PHMPT 2* order, DDOM/ALFOI have triaged resources to meet the July and August deadlines in *PHMPT 1* and *2*. ALFOI has once again reorganized its staff, leaving only a handful of staff working on all non-litigation FOIA requests. Additionally, DDOM is reassigning staff as available to assist in the review of some records.

29. ALFOI and DDOM have also been engaged in conversations with CBER'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. CBER continues to carefully consider the number of employees/contractors needed for these productions, especially given the extremely high costs to the agency. While CBER has advertised for new full-time employee positions, efforts to identify the availability of resources—particularly this quantity of resources during a time of budgetary uncertainty—are time-intensive and on-going.

30. Even if CBER is awarded the resources it hopes to add to ALFOI, receiving funds and hiring are merely the first steps in a labor-intensive process needed to train employees 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 alone takes several months (assuming a qualified candidate is found). Then, after a new employee is onboarded, it takes approximately two years for an employee to be fully trained so they can meaningfully contribute to ALFOI's disclosure efforts. In the meantime, more senior employees monitor new employees to ensure they perform straightforward 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 ALFOI 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 continued hiring and 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 (like Plaintiff's in this case), its resources remain limited by the lengthy ramp-up period for new employees.

31. ALFOI understands Plaintiff wants to receive records responsive to its FOIA request as quickly as possible, and ALFOI is committed to processing the request once it is in a position to do so. But given the substantial effect that *PHMPT 1* and *PHMPT 2* have had on ALFOI's workload, ALFOI does not have the bandwidth at this time to concurrently produce records in response to the request at issue in this litigation. In the coming months, ALFOI will continue its extraordinary efforts to maximize its chances of satisfying the court-ordered productions in *PHMPT 1* and *PHMPT 2* so it can resume processing Plaintiff's and other outstanding FOIA requests.

* * *

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

Executed on September 13, 2023.

Suzann H. Burk -S Digitally signed by Suzann H. Burk -S
Date: 2023.09.13 16:53:11 -04'00'

Suzann Burk
Director
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