UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, *Plaintiff,* v. FOOD AND DRUG ADMINISTRATION, *Defendant.*	Civ. A. No. 23-0220 (RDM)

JOINT STATUS REPORT

Pursuant to the Court's January 12, 2024, Memorandum Opinion and Order, ECF No. 25, staying the above-captioned matter for six months and ordering the parties to file a joint status report notifying the Court whether a further stay is appropriate, the parties, Plaintiff Children's Health Defense ("CHD") and Defendant United States Food and Drug Administration ("FDA"), respectfully submit the following:

PLAINTIFF'S POSITION

I. Introduction: A renewal of the stay should not be granted.

1. Since 2020, over 1.5 million adverse events have been reported to VAERS following receipt of a COVID-19 shot, including 37,544 deaths and over 130,000 serious adverse events.[1] CHD's FOIA request seeks records of FDA's efforts to determine the extent to which these events were *caused* by the shots—efforts that include Empirical Bayesian data mining (EB Mining) to look for safety signals suggesting possible causation, and follow-up investigations in collaboration with the CDC when a safety signal is detected and when serious events are

[1] See https://www.openvaers.com/covid-data (through April 26, 2024)).

reported. The need for these records is even greater now than it was in July 2022, when CHD sought them on an expedited basis.

2. Despite FDA's repeated claims that the shots are safe and are not the cause of the reported adverse events, FDA refuses to provide the records that would allow the public to test those claims or understand their basis. As of fall 2023, the estimated wait time before the FDA would even *begin* to process a vaccine-related request assigned to ALFOI's complex processing queue was at least two years.[2] And against plaintiffs like CHD who sue on vaccine-related requests because they would like FDA to respond before the records being sought qualify as history rather than news, FDA has asked to be excused from FOIA obligations due to the PHMPT production orders.

3. Meanwhile, FDA has failed to take any meaningful action to actually process the requests in ALFOI's complex processing queue. Indeed, it seems that ALFOI's FOIA processing system is designed to ensure that these requests do not get processed: since filing its motion to stay eight months ago, the FDA has processed approximately *40 of the 368 requests* that were ahead of CHD's in the complex queue–that is, an average of five requests a month.

4. During a meet-and-confer on June 12, 2024, the FDA, through counsel, informed CHD that it will not process CHD's request until the request arrives at the front of the complex queue

[2] To date, FDA has not responded to any of five other requests for records related to COVID vaccine safety that CHD has submitted to the agency since September 2022. These include #2022-6494, submitted 9.7.22, for records of safety monitoring through the Sentinel BEST system (now the subject of stayed litigation in this court); #2022-7832, submitted 11.3.22, for emails discussing myocarditis; #2023-294, submitted 1.9.23, for records of Pfizer vaccine manufacturing and quality control reports; #2023-2075, submitted 3.14.23, for records of monitoring underlying safety claims made to Florida Surgeon General Joseph Ladapo; and #23-10810, submitted 12.4.23, for records underlying communications regarding possible contamination of the vaccines.

at some unspecified date, or when the agency receives a court order to produce the records. This refusal extends to production of the 150 responsive EB mining records that FDA located over a year ago, the final processing of which will likely take less time than it took for the agency to complete its portion of this JSR. However, the mere fact that the FDA has assigned CHD's request to a processing queue that remains at a virtual standstill does not qualify as the diligence required for a continued *Open America* Stay. The time for a production order has arrived.

II. The FDA is not taking meaningful action to process requests in ALFOI's complex queue, and FDA's mere placement of CHD's request in the queue does not qualify as "diligence" for the purposes of a continued *Open America* stay.

5. In September 2023 (the end of FY 2023), ALFOI had 679 pending FOIA requests. *See* Declaration of Suzann Burk in *Children's Health Defense v. Centers for Disease Control & Prevention* No. 1:23-cv-00431-TNM, ECF 20-1, ¶ 19. Of the pending requests, at least 487 requests were in the complex queue. *See id*., ¶¶. 32, 35. In other words, *last fall, over 70% of ALFOI's pending FOIA requests were in the complex queue*, with the remaining 30% distributed among ALFOI's other five queues. This distribution suggested an urgent need for FDA to staff and organize ALFOI to ensure that requests in the complex queue do not languish indefinitely. But such staffing and organizing has not occurred.

6. On June 3, 2024, CHD emailed FDA through counsel to inquire about the status of CHD's request, and, more generally, about the FDA's efforts to process requests in ALFOI's complex queue, including any steps taken to reduce the backlog in the queue. In a meet-and-confer on June 12, CHD was informed that since October 2023, FDA has processed about 40 requests in the complex queue, which is an average rate of 5 requests per month. CHD also was informed that the FDA has taken no steps to address the backlog in the complex queue, other than hiring an unspecified number of new FOIA personnel for ALFOI. Moreover, according to FDA counsel, only a small handful of ALFOI's FOIA personnel consistently work on requests

other than the PHMPT production, as was the situation in October 2023, when just "a small team of six FTE's" had primary responsibility for all non-PHMPT FOIA requests. *See* Declaration of Suzann Burk, ECF 17-2, par. 24. Of the "small team" of FOIA workers working on non-PHMPT FOIA requests, FDA did not indicate to CHD how many–if any–are dedicated to processing requests within the complex queue.

7. In Fiscal Year 2023, FDA had 169 FOIA personnel, up from 131 in FY 2021. See https://www.foia.gov/data.html. Despite this, the FDA has assigned to just a miniscule portion of its FOIA workforce the responsibility for processing all non-PHMPT FOIA requests within ALFOI, including the hundreds of requests stagnating in ALFOI's complex queue. For the last eight months, the average processing rate in that queue has been just over one request per week. No wonder the backlog keeps growing.

8. The FDA has previously claimed that it is exercising due diligence in processing CHD's request because it maintains six processing queues, and at some point assigned CHD's request to the complex queue. *See* ECF 20, pp. 10-11. However, contrary to the FDA's interpretation, *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976) does not stand for the proposition that due diligence is satisfied merely because an agency sorts requests into processing queues, one of which the moral equivalent of cold storage, and uses a "first in first out" approach within that queue. Rather, in *Open America*, the Court commended the FBI's system because it "maintain[s] approximately the same rate of progress" for both simple and complex tracks. *Open America*, 547 F.2d at 613. By comparison, as set forth above, there is effectively no progress at all in the complex queue at the FDA.

9. Importantly, *Open America* did not involve allegations regarding a lack of due diligence:

> While neither we nor the District Court have undertaken examination of the fairness and efficiency of the FBI procedures, *neither have we been asked to do so*. There is no

> allegation by plaintiffs that the FBI procedure.. is anything but fair, orderly, and the most efficient procedure which can be adopted under the circumstances. *There is no allegation that the FBI has failed to allocate an appropriate number of personnel for the processing of Freedom of Information Act requests…*

Id. at 614 (emphasis added); *see also id*. at 615 ("no lack of *overall* diligence in handling the thousands of requests has been alleged by plaintiff") (emphasis in original).

10. Here, unlike the plaintiff in *Open America*, CHD *does* allege a lack of due diligence. Specifically, a FOIA system with a queue that reduces only 40 out of 487 requests over an eight-month period, and that represents 70% of all backlogged requests within ALFOI is neither efficient nor fair. The FDA's hiring of additional personnel to work on the PHMPT productions is an insufficient response to the PHMPT orders, especially where more than two years have passed since the first order was entered, and the bulk of ALFOI's non-PHMPT FOIA requests still remain unanswered. FDA has not exercised due diligence in the processing of any complex request that must wait in the queue that barely moves, including CHD's.[3]

11. Accordingly, the *Open America* court would have rejected the FDA's request for a continued stay for lack of due diligence. Consistent with *Open America*, rather than accepting FDA's request for an extension that is ultimately based upon the agency's failure to adequately address its own FOIA processing needs, this Court should put the public's needs first and hold the FDA to its transparency obligations under the FOIA.

[3] In addition to these general failures of diligence, FDA also has lacked diligence in responding to CHD's request in particular. As detailed in CHD's Opposition to FDA's Motion to Stay, ECF 19, the FDA's lack of diligence included the agency's initial outright denial of the request, claiming that any responsive records were protected by the "deliberative process" exemption, with no actual search for responsive records. As detailed in the Opposition memo, this denial violated numerous provisions of the FOIA and HHS FOIA-processing protocols. *See* ECF 19, pp. 30-34.

III. The need for the requested safety-monitoring records remains urgent, as the FDA continues to publicly tout COVID-19 vaccine safety based on the very safety monitoring efforts documented in those records.

12. When granting a stay in *Open America,* the court relied in part on the fact that the plaintiff's request did not involve an urgent need for the information. The court explained:

> Plaintiffs have alleged no urgency, have alleged no exceptional need, for the information they seek. Indeed, at oral argument counsel for plaintiffs was commendably frank in stating that the action of the District Court could not be defended on the ground of urgency or exceptional need, for the District Court made no such findings.

Open America at 614.

13. In the present case, however, CHD's July 2022 FOIA request sought expedited processing, and included detailed arguments regarding the urgent need for the records. *See* ECF 1-1, pp. 7-10. This need has only increased. As the number of injuries reported to VAERS continues to grow, even federal officials are recognizing the possible causal connection between the shots and serious injuries. For example, after downplaying the risks of the COVID shots for years, former FDA commissioner Janet Woodcock recently admitted that "some recipients experienced uncommon but 'serious' and 'life-changing' reactions *beyond those described by federal agencies.*" (emphasis added) *See* Apoorva Mandavilli, *Thousands Believe Covid Vaccines Harmed Them. Is Anyone Listening?* New York Times, May 3, 2024, https://www.nytimes.com/2024/05/03/health/covid-vaccines-side-effects.html#:~:text=Dr.%20Zimmerman's%20account%20is%20among,19%20percent%20have%20been%20reviewed.

14. Ironically, while refusing to provide records of the safety-monitoring efforts that underlie CHD's FOIA request, the FDA has continuously relied on those very safety-monitoring efforts when touting the safety of the COVID-19 shots. For example, in a 2023 letter that responded to Florida Surgeon General Joseph Ladapo's concerns regarding Florida VAERS reports, FDA

touted the shots' safety, claiming most adverse events reported to VAERS are caused by pre-existing conditions. *See* Letter from CDC and FDA to Joseph A. Ladapo, M.D., Ph.D. dated March 10, 2023 https://www.fda.gov/media/166159/download. The FDA's statements rely on the *very monitoring activities that underlie CHD's FOIA request*: "For signals identified in VAERS, physicians from FDA and CDC screen individual reports, inclusive of comprehensive medical record review. Most reports do not represent adverse events caused by the vaccine and instead represent a pre-existing condition that preceded vaccination or an underlying medical condition that precipitated the event." *See id*.

15. More recently, in February 2024, when CBER Director Dr. Peter Marks testified before Congress (*see Testimony of Peter Marks, M.D. Ph.D., Before the Select Subcommittee on the Coronavirus Pandemic Committee On Oversight and Accountability*, U.S. House of Representatives https://oversight.house.gov/wp-content/uploads/2024/02/FDA-SSCP-Vaccine-Safety-and-Surveillance-FDA-Written-Testimony-FINAL-Clean.pdf, (February 15, 2024)), his statements regarding vaccine safety, safety monitoring, and transparency included the following (all emphasis is added):

- "*Vaccine safety is closely and continuously monitored through multiple surveillance systems*, which alert both FDA and the Centers for Disease Control and Prevention (CDC) should a potential concern arise." *Id*. at 1.
- "FDA has consistently followed a science-driven process *with transparency in mind* when evaluating the safety and effectiveness of COVID-19 vaccine candidates." *Id.*
- *FDA "investigate[s] all events that potentially indicate a safety concern*…FDA and CDC have implemented a coordinated and overlapping approach for continuous safety monitoring of all COVID-19 vaccines using state-of-the-art methods." *Id.* at 3. *This approach includes analyzing reports from the VAERS system*, "a national safety monitoring system co-managed by the FDA and CDC." *Id.*
- "*FDA and CDC experts assess relevant data from serious reports and share important findings with each other*." *Id.* at 4.

16. Despite these and other statements regarding the safety and monitoring of COVID-19 vaccines, the FDA has yet to disclose any data or analysis in connection with its VAERS EB

mining and follow-up investigations. At this point, rather than expecting the public to simply take its word that the shots are safe, the FDA should fulfill its transparency promises and its statutory obligations, by producing the safety-monitoring records forthwith.

IV. Conclusion and Plaintiff's proposed order

17. For these reasons, CHD respectfully requests that the Court issue the following Order:

Defendant's request for a continued stay is DENIED.

Within 30 days of this order, Defendant shall

(1) Produce to Plaintiff the 150 EB records already identified as responsive to Plaintiff's request;

(2) Conduct all searches necessary to fulfill the remainder of Plaintiff's request;

(3) Submit a status report to this court, detailing

(a) Whether the EB records have been produced;

(b) What searches have been conducted;

(c) The volume of responsive records located;

(d) A proposed production schedule for the responsive records;

(e) Whether Plaintiff agrees with the proposed production schedule.

If Plaintiff disagrees with the proposed production schedule, Plaintiff may, within 10 days of Defendant's status report, submit an alternative proposal.

DEFENDANT'S POSITION

18. For the reasons explained below, the *Open America* stay previously ordered by this Court should remain in place, with the parties being directed to submit another joint status report in six months to apprise the Court of the FDA's ability at that time and in the foreseeable future to turn to Plaintiff's Freedom of Information Act ("FOIA") request. As detailed herein, in the near term

the FDA will not be able to handle Plaintiff's request due to the overwhelming demands presently confronting the agency as it does its utmost to satisfy the obligations imposed by another district court. The approach proposed herein will allow the Court to reappraise the stay each six months based upon the then-existing state of affairs, and the Court will then be able to determine the appropriate time to dissolve the stay.

19. FDA has been and continues to work at full capacity so that it can satisfy the unprecedented production order in *PHMPT & Stephanie and Patrick de Garay v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT II*"). The production order in *PHMPT II* requires FDA to produce at least 180,000 pages per month from December 1, 2023, to June 30, 2025. *See* Order, *PHMPT II* (ECF No. 38) (Jun. 12, 2023) (attached as Exhibit 1). However, to meet the June 2025 deadline, FDA needs to produce an average of 230,000 pages per month, a rate of production that is many orders of magnitude greater than anything any agency ever has encountered. *See* Declaration of Suzann Burk at 9, ECF No. 17-2. To date, FDA has been able to keep pace with this production mandate, but it has taken a tremendous amount of agency resources to do so. Ex. 2, Joint Status Reports filed in *PHMPT II* (ECF Nos. 39 (Sep. 1, 2023), 41(Nov. 30, 2023), 42 (Feb. 28, 2024), and 43 (May 28, 2024).

20. FDA hired six new employees in 2023 and to date has hired five new employees in 2024 to enhance its processing capabilities. These employees have been onboarded and are at various stages in their training. FDA also increased to twenty-six the number of contractors it has working to process records for *PHMPT II*. The majority of employees and all the contractors are working to satisfy the *PHMPT II* production mandate, leaving a small group of employees to work on all other Freedom of Information Act ("FOIA") requests that seek records maintained by FDA's Center for Biologics Evaluation and Research ("the Center"). As a result, the workload generated

by *PHMPT II* and the other FOIA requests currently pending before the Center remains overwhelming.

21. As of June 6, 2024, there were 323 FOIA requests ahead of CHD's FOIA request in the Center's Complex Track.

22. Currently, there are stays in effect in three other cases in this District involving FOIA requests for records maintained by the Center: *Wright v. Dep't of Health & Hum. Servs.*, Civ. A No. 22-1378 (RC); *Children's Health Defense v. FDA*, Civ. A. No. 23-2316 (TJK); and *Informed Consent Action Network v. FDA*, Civ. A. No. 23- 0219 (RBW). There are also motions to stay pending in two other cases: *Informed Consent Action Network v. FDA*, Civ. A. No. 23-3675 (JMC) and *Children's Health Defense v. CDC*, Civ. A. No. 23-0431 (TNM). FDA continues to evaluate whether motions to stay proceedings should be filed in other cases that involve FOIA requests for records maintained by the Center.

23. FDA does not have the capacity to process CHD's request at this time because it is working to satisfy the unprecedented production order in *PHMPT II*. Moreover, processing CHD's request at this time would be unfair to other requesters whose requests currently sit before CHD's request in the Complex Track and are also experiencing delays because of the *PHMPT II* production order. *See Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 615-16 (D.C. Cir. 1976) (agencies should "assign[] all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown," as that is the most "fair" approach). It is appropriate for this Court to "recognize[] and accommodate[] th[e] reality" that under present circumstances a quicker response to CHD's request is impracticable. *See Citizens for Responsibility & Ethics in Washington v. Federal Election Comm'n*, 711 F.3d 180, 189 (D.C. Cir. 2013). FDA accordingly respectfully requests that the Court extend the stay in this matter and proposes that the parties file a joint status

report on or before December 13, 2024, notifying the court whether a further continuation of the stay is appropriate at that time.

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Washington, DC

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