UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, *Plaintiff*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *Defendant*.	Civil Action No. 23-220 (RDM)

MEMORANDUM OPINION AND ORDER

On January 16, 2023, Plaintiff Children's Health Defense filed suit in an effort to compel Defendant U.S. Food and Drug Administration's ("FDA") to respond to its Freedom of Information Act ("FOIA") request for "records connected with safety monitoring of COVID-19 vaccines through the VAERS database." Dkt. 1-1 at 3. Now, the FDA moves to stay the case for eighteen months due to the "exceptional circumstances" presented by another entity's FOIA requests, Dkt. 17-1 at 4. Known in this Circuit as an *Open America* stay, named after the leading case on the subject, *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), the FOIA permits a court—upon a showing by an agency that "exceptional circumstances exist and that the agency is exercising due diligence in responding to the request"—to "allow an agency additional time to complete its review of the records" at issue. 5 U.S.C. § 552(a)(6)(C)(i).

The FDA argues that the *Open America* threshold has been satisfied, and it therefore contends that it is entitled to an eighteen-month stay. For the reasons that follow, the Court agrees that the standard has been met but is not convinced, at least at this stage in the proceeding,

that a period of eighteen months is appropriate. Accordingly, the Court **GRANTS** the Defendant's motion to stay in part and **DENIES** the motion in part.

In support of its motion to stay, the FDA points the Court to two orders issued in two unrelated FOIA cases before Judge Mark T. Pittman of the U.S. District Court for the Northern District of Texas, which the FDA contends prevent it from being able to respond to Plaintiff's FOIA requests before 2025. The first of these orders was issued in *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, No. 21-cv-1058 (hereafter "*PHMPT 1*"). The plaintiff there had brought suit under the FOIA seeking "expedited processing" of its request for documents relating to Pfizer's COVID vaccine. *PHMPT 1*, Dkt. 1 at 19 (Compl. ¶ 53). In an order issued on January 6, 2022, Judge Pittman directed the FDA to "produce . . . documents at a rate of 55,000 pages every 30 days, with the first production . . . due on or before March 1, 2022, until production is complete." *PHMPT 1*, Dkt. 35 at 3. By way of comparison, the FDA had proposed that it produce approximately 12,000 pages in four productions over several months and to produce 500 pages each month thereafter. Dkt. 22 at 12. The FDA's requested production rate was consistent with the range of production rates that this Court typically requires, even in cases involving substantial public interest; the court-ordered production rate far exceeded what is typical in this Court.

As of December 19, 2023, the FDA had fulfilled its obligations pursuant to that first order, *see PHMPT 1*, Dkt. 75 at 1–2 (noting as of December 19, 2023, the FDA had completed processing the 1,200,874 pages of records responsive to PHMPT's request). But completion of production in *PHMPT 1* has not relieved the FDA of an extraordinary production obligation because a second order in another case before Judge Pittman (involving the same plaintiffs and a

similar FOIA request) has replaced it. *See PHMPT v. FDA*, No. 22-cv-915 (hereafter "*PHMPT 2*"). That second order, issued on June 12, 2023, directs the FDA to:

> [P]roduce all documents related to Pfizer's 12 to 15-year-olds COVID-19 vaccine by January 2, 2024, on a rolling basis at a rate no fewer than (1) 35,000 pages per month in July, August, and September 2023, (2) 55,000 pages per month in October and November 2023, and (3) 180,000 pages per month thereafter.

PHMPT 2, Dkt. 38 at 1. The order also directs the FDA to "produce all documents related to Moderna's adult COVID-19 vaccine by June 30, 2025, at a rate no less than 75,000 pages per month in January 2024 and 180,000 pages per month thereafter." *Id*.

This second order has imposed on the FDA a production rate that the FDA characterizes—without contradiction—as "many orders of magnitude greater than anything any agency has ever encountered in a FOIA production order." Dkt. 17-1 at 14. Although the *PHMPT 1* order required the FDA to produce 55,000 pages per month, the *PHMPT 2* order requires the FDA to produce 360,000 pages per month from January 2024 onward—a more than six-fold increase of what was already an extraordinary burden. To comply with this court-mandated rate of production, the FDA "implemented sweeping organizational and work process changes, including, among other things, hiring contractors and additional full-time employees, . . . reorganizing staff, and diverting resources from processing other FOIA matters." Dkt. 17-2 at 8 (Burk Decl. ¶ 24). As of October 2023, the FDA's Access Litigation and Freedom of Information Branch ("ALFOI") had hired nine full-time contractors (and one part-time contractor), costing approximately $3.5 million. The ALFOI plans to hire an additional six employees, increasing its size by two-thirds—from nine full-time employees to fifteen full-time employees. Dkt. 17 at 13, 15. Almost all of these added resources have been devoted to fulfilling the agency's obligations under the *PHMPT* orders. *Id.* at 15.

But despite this additional manpower and reorganization, the FDA remains hard pressed to meet its production obligations. As the FDA explains in its motion to stay:

> Now, with *PHMPT 2* straining the nine full-time employees and 9.5 contractors assigned primarily to *PHMPT 1*, the Branch is working aggressively to meet concurrent production orders totaling 90,000 to 110,000 pages per month in the immediate coming months, a burden that will ramp up to 180,000 pages per month in December 2023. Since the *PHMPT 2* order issued, the Center has triaged resources to meet the July and August deadlines in *PHMPT 1* and *PHMPT 2*, once again reorganizing staffing and leaving only a handful of staff working on all non-litigation FOIA requests. Additionally, the Center's Division of Disclosure and Oversight Management is reassigning staff as available to assist in the review of the Branch-managed records.

Id. at 14. In sum, the FDA contends that the *PHMPT* orders have overwhelmed the agency's production capabilities to such an extent that the orders present "exceptional circumstances" as contemplated by § 552(a)(6)(C)(i). The Court agrees.

The D.C. Circuit has long interpreted § 552(a)(6)(C)(i) "to mean that 'exceptional circumstances exist' when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress," such that the agency's "existing resources are inadequate to deal with the volume of such requests within the time limits" set forth in the FOIA. *See Open America*, 547 F.2d at 616. And consistent with that interpretation, this Court has found "exceptional circumstances" to exist when agencies have seen an aberrational increase in the number or size of FOIA requests. *See Democracy Forward Found. v. Dep't of Justice*, 354 F. Supp. 3d 55, 59 (D.D.C. 2018) (explaining that to satisfy §552(a)(6)(C)(i), "an agency must show that the number of requests received in the relevant period was truly unforeseen and remarkable"); *see also, e.g., Elec. Frontier Found. v. Dep't of Justice*, 517 F. Supp. 2d 111, 119 (D.D.C. 2007) (finding "exceptional circumstances" when the "FBI [had] received an additional 1/3 as many requests per month" than it had received the previous year, and when "this increase

[had] been coupled with a significant and unexpected decrease in the staff available to process those requests").

Although the cases that apply *Open America* to find "exceptional circumstances" typically do so in the context of a rising *number* of FOIA requests, *see, e.g., Summers v. U.S. Dep't of Justice*, 925 F.2d 450, 452 (D.C. Cir. 1991) ("[T]he FBI had shown 'exceptional circumstances' for the tardy pace of its FOIA compliance, i.e., the large volume and extensive nature of FOIA requests the agency had received and was processing"), the Court sees no reason why *Open America*'s logic should not apply with equal force to a *single* court-ordered production schedule that has "deluge[d]" the agency's limited resources and has thus limited the agency's ability to respond to other FOIA requests, *cf. Elec. Frontier Found.*, 517 F. Supp. 2d at 118 ("[The DOJ] not[es] that when the FBI is required to comply with a court-ordered deadline, it must divert personnel who would otherwise be available for FOIA requests such as [the plaintiff's]. DOJ's argument is logical in the abstract."). The unprecedented rate at which the *PHMPT* orders require the FDA to produce records is exceptional, and it is, if anything more overwhelming than the extraordinary increase in FOIA workloads that past decisions have found sufficient to warrant stays. *See Democracy Forward Found.*, 354 F. Supp. 3d at 60 (finding a ten-fold increase in the number of FOIA requests to constitute exceptional circumstances). Moreover, the insufficiency of even the extraordinary steps the FDA has taken to devote increased resources to respond to PHMPT's requests—ALFOI has almost doubled its full-time staff—shows that the agency's existing resources are inadequate to respond to the "deluge" that the *PHMPT* orders have imposed on it. For these reasons, the Court agrees that the FDA has shown that "exceptional circumstances" are present.

The Court appreciates that it might seem unfair to the plaintiff in this case (as well as to other FOIA requesters) to see the bulk of the agency's resources devoted to satisfying the demands of a single requester, who obtained an extraordinary court order before others were able to obtain more limited judicial relief. But that order is in place, and it is beyond the jurisdiction or proper role of this Court to review a decision rendered by another district court. Nor would it be in the interests of comity or respect for the law for this Court to enter an order that would, at least in practical effect, conflict with the order entered by another district court. This Court must—and can only—take the record as it exists. Seen in that light, the Court can only conclude that the FDA is facing a Herculean undertaking that, despite the agency's best efforts, precludes it from processing Plaintiff's FOIA request in the usual course.

The presence of exceptional circumstances are not, however, in and of themselves sufficient for the Court to grant an *Open America* stay; the Court must also find that the agency is "exercising due diligence in responding to the request." 5 U.S.C. § 552(a)(6)(C)(i). The FDA explains that it has exercised such diligence by taking the "aggressive" steps described earlier: hiring both contractors and full-time staff, reorganizing existing resources, and seeking additional funding to continue to ramp up production even more. *See* Dkt. 17-2 at 8–10 (Burk Decl. ¶¶ 24–26, 30). In addition, the FDA notes that in processing FOIA requests, ALFOI uses a "multi-track" system in which "requests are placed in one or more of six queues based on volume, complexity, and/or subject matter, and requests in each queue are generally assigned to reviewers on a first-in, first-out basis." Dkt. 17-1 at 15. Both the onboarding and reassignment of new staff, as well as the first-in, first-out multi-track system for processing requests have been found sufficient to establish due diligence in other cases, *see Democracy Forward Found.*, 354 F. Supp. 3d at 62 (finding due diligence where an agency responded to the deluge of FOIA

requests by "reassigning other . . . staff to FOIA processing on an ad hoc basis," by making "modest staff additions to the FOIA team," and by "employ[ing] a multi-track, first-in, first-out process"); *Elec. Frontier Found.*, 517 F. Supp. 2d at 120 (finding that the FBI had exercised due diligence where the plaintiff's FOIA request had "been handled pursuant to the FBI's standard first-in/first-out procedure for assigning requests for review within each size-based queue"); *cf. Open America*, 547 F.2d at 616 ("The good faith effort and due diligence of the agency to comply with all lawful demands under the Freedom of Information Act in as short a time as is possible by assigning requests on a first-in, first-out basis, except those where exceptional need or urgency is shown, is compliance with the Act."), and are sufficient here.

With respect to Plaintiff's FOIA requests specifically, the FDA has also demonstrated that it has been diligent. It has explained that, to date, the FDA has completed its search for records responsive to two of the items in Plaintiff's FOIA requests, Dkt. 17-1 at 7, and that it reviewed 1,300 records that were potentially responsive to another item in those requests, Dkt. 15 at 3. Although the FDA has yet to complete searches for the remaining two items in Plaintiff's FOIA requests, Dkt. 17-1 at 8, and the agency has yet to review approximately 150 potentially responsive records, Dkt. 20 at 15, this progress on Plaintiff's broad request for vaccine information indicates that the FDA is exercising due diligence in processing the requests. Accordingly, the Court finds that the FDA has demonstrated that it has exercised due diligence in responding to Plaintiff's FOIA requests.

In opposing the stay, Plaintiff advances two arguments, neither of which the Court finds persuasive. First, it contends that "[t]he production burden ALFOI faces in the PHMPT litigation is . . . not a surprise, because . . . FDA's own regulations provide unambiguous notice that when the FDA approves a vaccine, licensing information must be disclosed quickly and as a

matter of course." Dkt. 19 at 37. This argument, however, misunderstands the basis for the Court's exceptional-circumstances finding: the FDA has shown that it has already taken extraordinary steps to comply with a court-ordered production schedule that is, in the words of the FDA, "*many orders of magnitude* greater than anything *any* agency has *ever* encountered," Dkt. 17-1 at 14 (emphasis added). Plaintiffs do not dispute this factual premise. Although it is conceivable that the FDA might have anticipated that it would face vaccine-related FOIA requests following its approval of COVID vaccines to combat the global pandemic then-raging, it could not have anticipated that a court would order it to produce records in response to COVID-vaccine-related FOIA requests at a rate that vastly outpaces what has *ever* been required of the FDA (or *any other* agency) in other FOIA cases.

Next, Plaintiff contends that the burdens ALFOI faces are a problem of the FDA's own making because the agency decided "to assign the substantial work of processing vaccine-related FOIA requests to ALFOI without providing ALFOI sufficient staff to shoulder that load." Dkt. 19 at 16. But "as a general matter, it is not the role of the judiciary to question how executive agencies request and allocate resources," *Democracy Forward Found.*, 354 F. Supp. 3d at 62; *see also id.* ("The court simply is not in a position . . . to fairly judge whether the agency's budgetary decision-making reflects an indifference to its FOIA obligations or is attributable to other political factors to which the court is not privy."), nor does the Court control congressional appropriations. Here, Plaintiff has not provided any evidence that the FDA has acted in bad faith or in derogation of its FOIA obligations by assigning vaccine-related requests to ALFOI or otherwise. To the contrary, the information the FDA has presented to the Court shows just the opposite—that the agency has been put in an extraordinarily difficult position and that it has

responded with extraordinary efforts. For those reasons, the Court understands Plaintiff's frustration, but is unpersuaded that the FDA has created the problem it now faces.

That said, the Court is mindful of the FOIA's purpose in mandating the "efficient, prompt, and full disclosure of information" by agencies, *Maydak v. U.S. Dep't of Justice*, 218 F.3d 760, 764 (D.C. Cir. 2000) (quoting *Senate of Puerto Rico v. Dep't of Justice*, 823 F.2d 574, 580 (D.C. Cir. 1987)). Accordingly, although the Court will grant the FDA's request for a stay, it will not do so for the eighteen-month period the agency requests. Instead, the Court will grant a six-month stay, subject to further consideration as events unfold. To the extent that the FDA maintains that the burden it faces in the Texas litigation is excessive, it should take it up with that court. It is not this Court's role to second guess another district court.

Accordingly, it is hereby **ORDERED** that the FDA's motion for a stay is **GRANTED**. It is further **ORDERED** that the case is **STAYED** for six months. The parties are **ORDERED** to file a joint status report on or before June 14, 2024, notifying the Court whether a further stay is appropriate.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: January 12, 2024