UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Civil Action No. 1:24-cv-1761 (CJN)

ORDER

This matter is before the Court on the FDA's motion for an eighteen-month stay of its obligations to respond to Plaintiff's FOIA request, which seeks clinical trial protocols related to the Boostrix vaccine against tetanus, diptheria, and pertussis. *See* ECF No. 13 (Stay Mot.); ECF No. 1 (Compl.). For the reasons discussed below, the Court will grant the motion in part and deny it in part.

Generally, an agency that receives a FOIA request must "determine within 20 days . . . whether to comply with such request," and then—if it decides to comply—make the requested records "promptly available." 5 U.S.C. §§ 552(a)(6)(A)(i), (C)(i). But "[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records." *Id.* § 552(a)(6)(C)(i). "'[E]xceptional circumstances exist' when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress" and its "existing resources are inadequate to deal with the volume of such requests within the [otherwise applicable] time limits." *Open Am. v. Watergate Special Prosecution Force*,

547 F.2d 605, 616 (D.C. Cir. 1976). And an agency can demonstrate its "due diligence" in complying with the requirements of FOIA by showing that it has a satisfactory "present procedure for processing FOIA requests"—such as one that categorizes requests by difficulty, seeks to proceed on a "first-in, first-out basis," and is staffed by an adequate number of personnel. *Id.* at 612–13.

The FDA has demonstrated that a stay under 5 U.S.C. § 552(a)(6)(C)(i), or an "*Open America* stay," is warranted here. In the past three years, the FDA received two court orders that together compelled it to produce approximately 5.7 million pages of COVID-19 vaccine records within a highly compressed timeframe. *See Pub. Health & Med. Professionals for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT I*"); *Pub. Health & Med. Professionals for Transparency v. FDA*, Civ. A. No. 22-915 (N.D. Tex.) ("*PHMPT II*"); *see also* ECF No. 13-1 (Burk Decl.) ¶¶ 7, 22. To satisfy the *PHMPT I* production order, the FDA was required to produce at least 90,000 pages per month from July 2023 to November 2023. Burk Decl. ¶ 7. And to satisfy the *PHMPT II* production order by the court's June 2025 deadline, the FDA will need to produce at least 230,000 pages per month between now and then. *Id.* ¶¶ 7, 25B. This unprecedentedly demanding production schedule—which has prompted the FDA to hire new employees and substantially reallocate its existing staff—far exceeds a "predictable" agency workload and thus constitutes "exceptional circumstances" within the meaning of FOIA. *Elec. Frontier Found. v. Dep't of Just.*, 517 F. Supp. 2d 111, 119 (D.D.C. 2007); *see also Child.'s Health Def. v. FDA*, 2024 WL 147851, at *3 (D.D.C. Jan. 12, 2024) (describing the same schedule as "more overwhelming than the extraordinary increase in FOIA workloads that past decisions have found sufficient to warrant stays"); Burk Decl. ¶¶ 24, 26.

The FDA has also exercised due diligence in responding to the FOIA requests it receives. FOIA requests submitted to the FDA are placed into one of six "queues" based on their "volume, complexity, or subject matter," and requests in each queue are generally processed in the order submitted. Burk Decl. ¶¶ 12–13. These standard protocols, in addition to the FDA's efforts to hire new staff in the wake of the *PHMPT I* and *PHMPT II* orders, "have been found sufficient to establish due diligence in other cases . . . and are sufficient [to do so] here." *Child.'s Health Def.*, 2024 WL 147851, at *3.

It is clear that an *Open America* stay of some duration is appropriate. But the eighteen-month stay sought by the FDA is too long, at least at present. As Plaintiff notes, production in the *PHMPT* matters will be completed by June 2025, and the FDA should have a better sense of its capacity to process Plaintiff's request after that time. *See* ECF No. 15 (Opp.) at 1. The Court will therefore stay this case only until the June 2025 deadline has passed, subject to further consideration with the benefit of new information following that date. It is accordingly

ORDERED that Defendants' Motion to Stay, ECF No. 13, is **GRANTED IN PART AND DENIED IN PART**;

ORDERED that this action is **STAYED** for approximately eight months, until and including July 21, 2025, with respect to any FDA processing of records (i.e., search, review, and redaction) for Plaintiff's FOIA Request No. 2020-7656; and it is further

ORDERED that the Parties shall file a joint status report on or before July 23, 2025, stating their positions on whether the stay should be lifted and, if so, proposing a schedule for further proceedings. If circumstances change while the case is stayed that warrant lifting the stay or otherwise affect the posture of this case, the parties may file a joint status report.

SO ORDERED.

November 20, 2024

CARL J. NICHOLS
United States District Judge