

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Case No. 1:25-cv-0827 (JMC)

ORDER

The Court ORDERS that Defendants’ Motion to Stay, *see* ECF 14, is GRANTED in part and DENIED in part: for the reasons stated below, this matter shall be stayed for approximately six months until and including Friday, February 27, 2026. It is further ORDERED that the parties shall file a joint status report on or before February 27, 2026, 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.

FOIA provides that agencies shall make requested records “promptly available,” 5 U.S.C. § 552(a)(3)(A), 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). An agency may obtain a stay of proceedings under that provision if it “is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it ‘is exercising due diligence’ in processing

the requests.” *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976). Here, the FDA has shown both exceptional circumstances and due diligence justifying an *Open America* stay.

Turning first to exceptional circumstances: Plaintiff requests records from FDA’s Center for Biologics Evaluation and Research (CBER). But CBER has been ordered by another court to produce approximately 9.1 million pages of COVID-19 vaccine records in a compressed timeframe—“an extraordinary workload . . . that FDA could not have predicted.” ECF 14-2 at 3-4 (describing litigation in *Pub. Health & Med. Pros. for Transparency v. FDA*, No. 21-CV-1058 (N.D. Tex.) (“*PHMPT I*”), and *Pub. Health & Med. Pros. for Transparency v. FDA*, No. 22-CV-0915 (N.D. Tex.) (“*PHMPT II*”). “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.” *Child. ’s Health Def. v. FDA*, No. 23-CV-220, 2024 WL 147851, at *3 (D.D.C. Jan. 12, 2024).

The FDA must also demonstrate due diligence. The agency states that it has “a multi-track process for handling FOIA requests . . . and requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis,” and that it has undertaken “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.” ECF 14-1 at 18; ECF 14-2 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... and are sufficient here.” *Child. ’s Health Def.*, 2024 WL 147851, at *3.

Because the FDA has demonstrated both exceptional circumstances and due diligence, an *Open America* stay is warranted here. This Court’s conclusion is consistent with the conclusion of at least 10 other courts who have issued stays in similar cases involving the FDA. *See* ECF 14-2 at 17–19 (collecting cases).

However, the Court is sensitive to Plaintiff’s concern that staying this case for 18 months, as FDA requests, could “render the disclosures stale and the public debate irretrievably distorted.” ECF 16 at 38. The Court also notes that some other courts in this district faced with similar requests for an 18-month stay have instead imposed—at least initially—a six-month stay. *See Child. ’s Health Def.*, 2024 WL 147851, at *5 (staying case for six months); *Child. ’s Health Def. v. Ctrs. for Disease Control & Prevention*, No. 23-CV-00431, 2024 WL 3521593, at *6 (D.D.C. July 24, 2024) (staying case for six months); May 24, 2024 Minute Entry, *Informed Consent Action Network v. FDA*, No. 23-CV-219 (D.D.C.) (staying case for six months); *but see* Oct. 13, 2023 Order, *Wright v. Dep’t of Health & Hum. Servs.*, No. 22-CV-1378 (D.D.C.) (granting unopposed motion for 18-month stay); Dec. 13, 2023 Minute Order, *Child. ’s Health Def. v. FDA*, No. 23-CV-2316 (D.D.C) (staying case for 18 months). The Court therefore finds it appropriate to impose a six-month stay at this time.

SO ORDERED.

JIA M. COBB
United States District Judge

Date: August 28, 2025