UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Informed Consent Action Network v. Food and Drug Administration

Informed Consent Action Network · No. Civil Action No. 25-cv-00832 (TSC) · Decided February 5, 2026

SUMMARY

The United States District Court for the District of Columbia considered Defendants' motion to stay a FOIA action brought by Informed Consent Action Network against the FDA and HHS. The court found exceptional circumstances and due diligence supporting an Open America stay, but denied the requested eighteen-month duration. The court stayed the matter until October 1, 2026, and ordered the parties to file a joint status report by that date.

CASE DETAILS

COURT	United States District Court for the District of Columbia
WRITING FOR THE COURT	Tanya S. Chutkan
JURISDICTION	United States District Court for the District of Columbia
DECIDED	February 5, 2026
DOCKET	Civil Action No. 25-cv-00832 (TSC)
DISPOSITION	other
PROCEDURAL POSTURE	Plaintiff brought a Freedom of Information Act action seeking records from the FDA and HHS. After the complaint and answer were filed, defendants moved to stay the proceedings for eighteen months because of competing FOIA production obligations imposed by a Texas federal court.
STANDARD OF REVIEW	The court applied the statutory standard for an Open America stay, requiring the agency to demonstrate exceptional circumstances and due diligence in responding to the FOIA request.
PRECEDENTIAL VALUE	published

TOPICS

administrative law · judicial review of agency action · civil procedure

PRACTICE AREAS

administrative law · Freedom of Information Act · civil procedure

QUESTIONS PRESENTED

1. Whether the court may stay a FOIA action under the Open America doctrine when the agency demonstrates exceptional circumstances and due diligence.
2. Whether defendants demonstrated exceptional circumstances warranting a stay of proceedings.
3. Whether defendants demonstrated due diligence in processing FOIA requests.
4. Whether the requested eighteen-month stay was warranted, or whether a shorter stay was appropriate.

HOLDINGS

1. A court may retain jurisdiction and allow an agency additional time to complete its FOIA review when the agency demonstrates exceptional circumstances and due diligence.
2. Defendants demonstrated exceptional circumstances because the FDA office processing the request faced an unforeseeable and unprecedented workload caused by Texas-court production orders, compounded by increased FOIA requests and related litigation.
3. Defendants demonstrated due diligence by maintaining a multi-track, generally first-in, first-out processing system and taking steps to hire, train, reassign, and organize personnel and resources to address the workload.
4. An eighteen-month stay was not warranted, but a stay through October 1, 2026, approximately eight months from the order, was necessary and appropriate.

KEY QUOTATIONS

> *"Such "exceptional 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.""* (at 2)

> *"Based on the foregoing, it is hereby ORDERED that this matter shall be stayed for approximately eight months, until and including October 1, 2026."* (at 8)

FACTUAL BACKGROUND

Plaintiff submitted a complex FOIA request seeking emails containing specified terms and involving specified FDA employees or addresses. The request was assigned FOIA number 2020-819 and placed on the Complex Track; the FDA provided only a partial response in 2022. Defendants showed that the FDA office responsible for processing the request was also subject to Texas-court orders requiring production of approximately 9.1 million pages concerning COVID-19 vaccines by October 1, 2026, while managing an increased FOIA workload and related litigation.

PROCEDURAL HISTORY

Plaintiff filed a FOIA request in January 2020 and received a partial response in 2022. Plaintiff filed this action on March 20, 2025, alleging that defendants had not completed their determination or produced the requested records. After defendants answered, they moved for an eighteen-month stay. The court granted the motion in part and denied it in part, ordering a stay through October 1, 2026, followed by a joint status report.

DISPOSITION

other

CASES CITED

- Open Am. v. Watergate Special Prosecution Force, 547 F.2d 605 (D.C. Cir. 1976)
- SafeCard Servs., Inc. v. Sec. and Exch. Comm'n, 926 F.2d 1197, 1200 (D.C. Cir. 1991)
- Landis v. N. Am. Co., 299 U.S. 248, 254 (1936)
- Informed Consent Action Network v. Food and Drug Admin., No. 25-cv-823, 2025 WL 2938703 (D.D.C. Oct. 16, 2025)
- Child.'s Health Def. v. FDA, No. 23-cv-220, 2024 WL 147851 (D.D.C. Jan. 12, 2024)
- Informed Consent Action Network v. Food and Drug Admin., No. 24-cv-1761, 2024 WL 4836405 (D.D.C. Nov. 20, 2024)
- Informed Consent Action Network v. Food and Drug Admin., No. 25-cv-0827, 2025 WL 2480080 (D.D.C. Aug. 28, 2025)

OPINION

Informed Consent Action Network v. Food and Drug Administration
PER CURIAM.
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA
INFORMED CONSENT ACTION
NETWORK,
Plaintiff, Civil Action No. 25-cv-00832 (TSC) v.
FOOD AND DRUG ADMINISTRATION,
et al. Defendants.
OPINION AND ORDER

On March 20, 2025, Plaintiff Informed Consent Action Network brought this action against the Food and Drug Administration ("FDA") and the United States Department of Health and Human Services ("HHS"), seeking records it previously requested under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). See Compl. ¶¶ 6–11, ECF No. 1. After the Complaint and Answer were filed, Defendants moved to stay proceedings for eighteen months due to significant records demands imposed on Defendants by a district court in Texas. Mot. to Stay at 1–3, ECF No. 13. For the reasons below, Defendants' Motion is GRANTED in part and DENIED in part.

I. BACKGROUND

On January 23, 2020, Plaintiff filed a FOIA request, seeking "[e]ach and every email communication between January 1, 2017, and the present" that included the terms "Informed Consent Action Network" or "ICAN" or "Bigtree" or "Del" and also included certain FDA Page 1 of 8 employee names or email addresses in the "To," "From," "Cc" or "Bcc" line. Compl. ¶ 6; Ex.

1, ECF No. 1-1. Plaintiff's request was assigned a FOIA number, 2020-819, Compl. ¶ 7, and placed in the "Complex Track" for requests due to the time expected to process it, Decl. of Suzann Burk ("Burk Decl.") ¶ 40, ECF No. 16. After some communication between the parties, Defendant sent Plaintiff a partial response to its FOIA request in 2022. Compl. ¶ 10; Ex. 5 at 1– 4, ECF No. 1-5. Since that initial response, however, Defendants have allegedly failed to "determine whether to comply with the request," "notify Plaintiff of any such determination or the reasons," "advise Plaintiff of the right to appeal any adverse determination not to comply with the request," or "produce the requested records or otherwise demonstrate that the requested records are exempt from disclosure." Compl. ¶ 11. In light of these asserted failures, Plaintiff filed this action to compel the production of their requested documents. Defendants filed their Answer on May 21, 2025, ECF No. 11, and, on June 16, 2025, moved for an eighteen-month stay of proceedings from the date of the court's order, see Mot. to Stay. Plaintiff opposes the motion to stay. See Pl.'s Opp'n, ECF No. 15.

II. LEGAL STANDARD

When an agency receives a request for records under FOIA, it shall "determine within 20 days . . . whether to comply with such request." 5 U.S.C. § 552(a)(6)(A)(i). If the agency decides to comply, it must make the requested records "promptly available." Id. § 552(a)(6)(C)(i). Where an agency demonstrates that "exceptional circumstances exist" and that it is "exercising due diligence in responding to the request," however, courts "may retain jurisdiction and allow the agency additional time to complete its review of the records." Id. Such "exceptional Page 2 of 8 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). Agencies can demonstrate "due diligence" by showing a satisfactory "present procedure for processing FOIA requests," including, for instance, a process that separates requests by difficulty, proceeds on a "first-in, first-out basis," and designates an adequate number of personnel. Id. at 612–13. When considering a request for an Open America stay, "[a]gency affidavits are accorded a presumption of good faith, which cannot be rebutted by purely speculative claims." SafeCard Servs., Inc. v. Sec. and Exch. Comm'n, 926 F.2d 1197, 1200 (D.C. Cir.1991) (citations and internal quotation marks omitted).

III. ANALYSIS

Defendants have shown both exceptional circumstances and due diligence justifying an Open America stay of at least eight months, but not the eighteen months they request. 1 At the outset, the court rejects Plaintiff's argument that "FOIA's enforcement provision, 5 U.S.C. § 552(a)(4)(B), does not authorize judicial stays." Pl.'s Opp'n at 8. As Chief Judge Boasberg aptly explained in his opinion granting an Open America stay in another one of Plaintiff's FOIA cases, Plaintiff's "unsupported statutory reading" "runs headlong into a wall of textual evidence and precedent" and otherwise fails to account for the longstanding doctrine that "this Court has no authority to

reinterpret a statute contrary to existing circuit precedent." Informed 1 Because the court concludes that an Open America stay is warranted in this case, it declines to consider Defendants' alternative request for a stay through the court's inherent docket- management power, see Landis v. N. Am. Co., 299 U.S. 248, 254 (1936). Page 3 of 8 Consent Action Network v. Food and Drug Admin., No. 25-cv-823, 2025 WL 2938703, at *2 (D.D.C. Oct. 16, 2025). The court agrees with Defendants that exceptional circumstances exist due to the unforeseeable and unprecedented workload resulting from several orders entered in two FOIA cases pending in the Northern District of Texas. Mot. to Stay at 9–14. Specifically, Defendants aver that the entity responsible for processing Plaintiff's FOIA request, the disclosure office for the Center for Biologics Evaluation and Research ("CBER"), has been and remains subject to increasing production rates ordered by the Texas court, ranging from a total of 90,000 to 180,000 pages per month since July 2023. See Burk Decl. ¶¶ 8–10 (addressing workload resulting from production orders 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")). This production rate far exceeds what courts in this district typically require and has forced CBER to reallocate limited staff and resources to meet the resulting workload demand. Id. ¶ 11. By way of example, "the common practice for courts in this district, whose FOIA docket dwarfs that of any other district in the country, is to require processing 300– 500 pages per month — orders of magnitude below what the judge required in the PHMPT litigation." Informed Consent Action Network., 2025 WL 2938703, at *3 (collecting cases). Moreover, during the pendency of the PHMPT litigation, "the number of FOIA requests received by [CBER's disclosure office] reached an all-time high of 633 requests in one fiscal year while FOIA litigation climbed." Def.'s Reply at 12–13, ECF No. 17 (citing Burk Decl. ¶ 27). Plaintiff counters that these burdens were foreseeable and otherwise of Defendants' own making because (1) the FDA initially withheld certain documents that the Texas court later ordered Page 4 of 8 disclosed in PHMPT I, and (2) the FDA exceeded the required monthly production rate in PHMPT II. See Pl.'s Opp'n at 19. But even if Defendants were on notice of the workload resulting from the recent overall uptick in FOIA requests, a position that other judges have rejected, see Informed Consent Action Network., 2025 WL 2938703, at *3 (explaining that there did not "appear to be either cyclical patterns of requests or a period of steady increase that would have put CBER on notice that a period of acceleration [in FOIA requests] was coming"), there was no way for Defendants to predict or otherwise prepare for the extreme rate of production that the Texas court initially required, and later extended, over the course of the PHMPT litigation. See e.g., PHMPT II, ECF No. 49 (May 2025 Joint Status Report noting that the court's orders in PHMPT I, as applied in PHMPT II, would "substantially increase the number of responsive documents"), id., ECF No. 52 (June 2025 Amended Court Order extending production rate of 180,000 documents per month beyond the previously anticipated June 30, 2025, deadline in light of new responsive documents). And insofar as Defendants could have predicted the volume of additional responsive documents, they have engaged in good faith

efforts to triage the substantial demands of the PHMPT litigation and their backlog of other FOIA requests. See, e.g., Burk Decl. ¶¶ 11, 32, 34–36. Moreover, the court declines to discredit Defendants' articulation of their current workload based on Plaintiff's observation that they were capable of meeting their monthly court-ordered obligations in separate litigation. Taken together, the Texas court's orders require CBER to produce approximately 9.1 million pages of documents relating to the COVID-19 vaccine by October 1, 2026, representing a sixty-percent increase from the 5.7 million pages that the court initially ordered produced. Burk Decl. ¶ 10. This "unprecedented rate at which the PHMPT orders require the FDA to produce Page 5 of 8 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). Numerous judges on this court have found that a stay is warranted under the circumstances facing CBER's disclosure office in managing its pending FOIA requests, see Burk Decl. ¶ 38 (collecting cases), many of which were initiated by Plaintiff, 2 see, e.g., Informed Consent Action Network, 2025 WL 2938703, at *4; Informed Consent Action Network v. Food and Drug Admin., No. 24-cv-1761, 2024 WL 4836405, at *1 (D.D.C. Nov. 20, 2024); Informed Consent Action Network v. Food and Drug Admin., No. 25-cv-0827, 2025 WL 2480080, at *1 (D.D.C. Aug. 28, 2025). The court sees no reason to depart from the consensus of the judges in this district in finding that the workload imposed on CBER by the Texas court's orders, compounded by an overall increase in FOIA requests and related litigation, see Burk Decl. ¶¶ 26–27 (documenting substantial increases since FY 2019 in CBER's FOIA request docket and related litigation), demonstrate "exceptional circumstances." The court also finds that Defendants have demonstrated "due diligence" in complying with FOIA's requirements. For instance, Defendants aver that CBER's disclosure office employs a multi-track process for handling FOIA requests, in which the office places requests in one or more of six queues "based on the volume, complexity, or subject matter of the requested records." Id. ¶ 17. Requests within each of these queues are "generally assigned to reviewers for processing on a first-in, first-out basis." Id. ¶ 18. Defendants have also undertaken extra efforts to hire and train new staff in light of the Texas court's orders. See id. ¶¶ 32, 35. Specifically, Defendants state that 2 According to Defendants' declaration, Plaintiff has filed approximately 350 FOIA requests since 2019 and is the plaintiff in twenty-three of the twenty-four open lawsuits seeking CBER records. Burk Decl. ¶ 29. Page 6 of 8 "CBER undertook 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 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." Id. ¶ 35. Plaintiff argues that the court's due diligence inquiry should focus on Defendants' diligence in relation to the specific FOIA request in this action, see Pl's Opp'n at 23, and may not be satisfied if the agency has not yet commenced document review, see id. at 24–26. But even if the court were to adopt Plaintiff's approach, Defendants' efforts to address other requests

necessarily implicates their ability to respond to Plaintiff's since, among other things, Plaintiff's request is currently on the "Complex Track" and sits behind twenty-three earlier requests. Burk Decl. ¶¶ 39, 43. When presented with the same evidence of CBER's efforts to balance the demands of the PHMPT litigation with its other FOIA obligations, several other judges in this district have determined that such efforts constitute due diligence. See Child.'s Health Def., 2024 WL 147851, at *3 ("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."); Informed Consent Action Network, 2025 WL 2938703, at *4 (same). The court concludes the same here. The court is, of course, wary of granting CBER a blanket exception to the FOIA's requirements and shares the concerns raised by other judges in this district regarding fairness to other FOIA plaintiffs. See Child.'s Health Def., 2024 WL 147851, at *3. Moreover, Plaintiff raises justifiable concerns over the public's often diminishing interest in FOIA-requested documents over time. See Pl.'s Opp'n at 27. But the practical effects of the PHMPT litigation on Page 7 of 8 CBER's ability to address other pending requests, including Plaintiff's, cannot be ignored. Defendants state that they expect to meet PHMPT production orders by the Texas court's October 1, 2026, deadline. Mot. to Stay at 11. The court believes that a stay through this deadline is both necessary to ensure adequate document review as well as appropriate under the circumstances and given Defendants' demonstrated diligence.

IV. CONCLUSION

Based on the foregoing, it is hereby ORDERED that this matter shall be stayed for approximately eight months, until and including October 1, 2026. It is FURTHER ORDERED that the parties shall file a joint status report on or before October 1, 2026, informing the court of the status of Plaintiff's FOIA request, as well as the parties' positions on whether the stay should be extended, and, if not, proposing a schedule for further proceedings. Date: February 5, 2026 Tanya S. Chutkan TANYA S. CHUTKAN

United States District Judge Page 8 of 8