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. 24-1905 (JDB)**

MEMORANDUM OPINION AND ORDER

In 2020, Informed Consent Action Network ("ICAN") submitted a FOIA request for records from the FDA's Center for Biologics Evaluation and Research ("CBER") regarding pertussis, also known as whooping cough. See Compl. [ECF No. 1] ¶ 6; Supp. Decl. of Suzann Burk ("Supp. Burk Decl.") [ECF No. 21-1] ¶ 24. When CBER did not fulfill that request by June 2024, ICAN filed this suit. Compl. ¶ 8. On February 4, 2025, the Court stayed this case for six months. See Feb. 4, 2025 Stay Order [ECF No. 17] at 5. The Court renewed the stay for six months and then again for eight months. See Aug. 7, 2025 Stay Extension Order [ECF No. 20] at 4; Feb. 12, 2026 Stay Extension Order [ECF No. 22] at 5. Defendants now request that the Court extend the stay for twelve more months. Joint Status Report ("JSR") [ECF No. 24] at 4. ICAN asks the Court to lift the stay and to order defendants to produce all records responsive to its FOIA request within 30 days. Id.

The Court will renew the stay because defendants continue to face "exceptional circumstances" and to exercise "due diligence" in processing ICAN's FOIA request. 5 U.S.C. § 552(a)(6)(C)(i); see Open Am. v. Watergate Special Prosecution Force, 547 F.2d 605, 616

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(D.C. Cir. 1976). Consistent with several of its prior orders, however, the Court will stay the case for six months, not the twelve months defendants request. The Court will also require the parties to file a joint status report before the stay expires that proposes a schedule for FDA's processing of records responsive to ICAN's FOIA request in this case.

BACKGROUND

In its initial stay order, the Court concluded that a stay was warranted because defendants faced exceptional circumstances and were acting diligently in responding to ICAN's and other FOIA requests. See Feb. 4, 2025 Stay Order at 2–4. The Court explained that defendants had "been deluged with FOIA requests" since the COVID-19 pandemic. Id. at 2 (citation modified). "In particular, orders in two" Northern District of Texas "cases alone ha[d] compelled" CBER's FOIA unit "to produce over 5.7 million pages of responsive records within a compressed timeline." Id. (citing Pub. Health & Med. Pros. for Transparency v. FDA, Civ. A. No. 21-1058 (N.D. Tex.) ("PHMPT I"); Pub. Health & Med. Pros. for Transparency v. FDA, Civ. A. No. 22-0915 (N.D. Tex.) ("PHMPT II")); see Feb. 12, 2026 Stay Extension Order at 1. The Texas litigation required FDA "to allocate many employees to handle the accelerated production schedule" "on top of an increase in FOIA requests" in other cases, resulting in "a far from 'routine backlog of FOIA requests.'" Feb. 4, 2025 Stay Order at 2–3 (quoting Elec. Frontier Found. v. Dep't of Just., 517 F. Supp. 2d 111, 119 (D.D.C. 2007)). The Court determined that FDA was "exercising the due diligence necessary" for a stay under these exceptional circumstances, including by placing ICAN's FOIA request "in one of six queues" for processing "on a first-in, first-out basis" and by

taking "aggressive efforts to reorganize staff and hire contractors and additional full-time employees." Id. at 3 (citation modified).[1]

In August 2025, the Court extended the stay for six months. August 7, 2025 Stay Extension Order at 4. Exceptional circumstances persisted because, even though FDA had recently completed a production in PHMPT I, "doing so required dedicating manpower to produce 600,000 pages" amid a "hiring freeze" and "staff departures," and FDA "still face[d] an order [in PHMPT II] requiring it to produce 2.8 million additional pages by October 26, 2025." Id. at 3. Defendants continued to act diligently by placing FOIA requests "in one of six queues and processing them on a first-in, first-out basis" and "tak[ing] steps to reorganize and acquire new staff to handle [the] backlog." Id.

Most recently, in February 2026, the Court renewed the stay for eight months, until October 2026. See Feb. 12, 2026 Stay Extension Order at 5. In requesting an additional extension, defendants had pointed to supplemental orders in PHMPT II "requiring CBER to produce 2.8 million more pages by October 1, 2026, as well as reductions in force and hiring freezes that ha[d] hobbled CBER's efforts to grow its FOIA unit." Id. at 2. ICAN did "not dispute that PHMPT I and II ha[d] created extraordinary circumstances." Id. at 3. The Court determined that defendants were diligently responding to those circumstances by triaging FOIA requests into queues; handling requests on a first-in, first-out basis; and undertaking "aggressive efforts to hire and train additional" FOIA personnel, such as "onboard[ing] seven contractors who will primarily process non-PHMPT requests, including 'Complex Track' requests such as ICAN's." Id. at 4.[2]

[1] FDA placed ICAN's FOIA request, which it designated as FOIA Request No. 2020-7162, in the "Complex Queue." Third Decl. of Suzann Burk ("Third Burk Decl.") [ECF No. 24-1] ¶¶ 4, 17. As of October 8, 2026, ICAN's request is number 35 in that queue. Id. ¶ 17.

[2] The Court also rejected ICAN's argument that FOIA does not authorize judicial stays. See Feb. 12, 2026 Stay Extension Order at 3–4.

Defendants now seek an extension of the stay for a further 12 months. They argue that even though CBER completed a PHMPT II production on October 1, 2026, "the effects of the … production orders" in both PHMPT "cases on CBER's Complex Queue backlog are ongoing, given the significant resources CBER has had to allocate to those cases." JSR at 7. ICAN opposes the request and contends that exceptional circumstances no longer exist now that defendants have completed the court-ordered productions in PHMPT I and PHMPT II. Id. at 2–3.

LEGAL STANDARD

By statute, agencies must "determine within 20 days … whether to comply" with FOIA requests. 5 U.S.C. § 552(a)(6)(A)(i). If an agency decides to comply, it must make the requested records "promptly available." Id. § 552(a)(6)(C)(i). But where an agency demonstrates that "exceptional circumstances exist" and that it is "exercising due diligence in responding to the request," courts "may retain jurisdiction and allow the agency additional time to complete its review of the records." Id. "[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., 547 F.2d at 616. The "due diligence" requirement may be met 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, 616.

ANALYSIS

An additional six-month stay is warranted. First, "Defendants' circumstances remain exceptional." Aug. 7, 2025 Stay Extension Order at 3. For years, CBER had to dedicate significant FOIA resources to comply with the production orders in PHMPT I and II, even as it "experienced

a substantial increase in the overall number of FOIA requests and amount of FOIA litigation from fiscal year 2019 to fiscal year 2025" and faced staffing challenges. Third Burk Decl. ¶¶ 9, 13; see Supp. Burk Decl. ¶¶ 10, 22, 26 (comparing CBER FOIA workload statistics from 2019 to 2025 and detailing several staffing issues).[3] The combination of CBER's PHMPT workload, increased CBER FOIA requests overall, and staffing constraints has resulted in a CBER FOIA backlog that is dramatically higher than it was at the end of fiscal year 2019. See Third Burk Decl. ¶ 10 ("As of October 1, 2026, the total number of CBER FOIA requests pending across all six tracks is 690."); Supp. Burk Decl. ¶ 22 (noting that CBER's FOIA unit had 83 pending FOIA requests at the end of fiscal year 2019). Even though CBER can devote more personnel to other FOIA matters now that it has fulfilled the PHMPT production deadlines, it will need time to work through the backlog. And neither ICAN nor defendants claim that CBER has the resources to process FOIA requests within the statutory time limits. In short, CBER continues to be "deluged with" an enormous "volume of requests for information," and its "existing resources are inadequate to deal with" that volume within normal FOIA time limits. Open Am., 547 F.2d at 616.[4]

Second, CBER continues to exercise due diligence in processing ICAN's and other FOIA requests. As it did with ICAN's request, CBER still places requests into one of six queues and "operate[s] its six FOIA tracks on a generally first-in, first-processed basis." Third Burk Decl.

[3] "The increase in pending FOIA requests was due in large part to requests for records related to the COVID-19 pandemic." Supp. Burk Decl. ¶ 22.

[4] ICAN argues that the "high volume of requests" reflects "the type of 'predictable agency workload' that 5 U.S.C. § 552(a)(6)(C)(ii) excludes" from the definition of "exceptional circumstances." JSR at 4. Even if CBER's current workload were predictable—an issue the Court does not now decide—the FOIA provision ICAN invokes would support extending the stay. Section 552(a)(6)(C)(ii) states that exceptional circumstances do "not include a delay that results from a predictable agency workload of [FOIA] requests," "unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." CBER has demonstrated such progress. "As of October 1, 2026, the total number of CBER FOIA requests pending across all six tracks is 690," "an approximately 30% decrease in the total CBER FOIA backlog from the 1013 requests pending as of September 30, 2025." Third Burk Decl. ¶ 10. Cutting the backlog by 30% over a one-year period, while simultaneously handling extraordinary production demands in the PHMPT litigation and contending with staffing issues, constitutes reasonable progress sufficient to support a six-month stay.

¶ 14. "FDA's employment of this process is alone evidence the agency is exercising due diligence." Feb. 4, 2025 Stay Order at 3 (citing Edmond v. U.S. Att'y, 959 F. Supp. 1, 3 (D.D.C. 1997); Open Am., 547 F.2d at 616). And CBER's "[e]fforts to hire, train, and retain staff to process CBER FOIA requests are ongoing." Third Burk Decl. ¶ 13. CBER (1) "expects to reallocate seven staff employees who were primarily working on PHMPT II to focus on processing other FOIA requests that are in litigation," (2) "onboarded and began training another contractor who was working on PHMPT II and will now focus on other litigation requests," and (3) "received approval to extend the contract of its approximately fifteen contractors to August 2027." Id. Finally, FDA recently "began the process of transitioning each of FDA's FOIA components, including CBER's disclosure office, into a unified office to improve management of FOIA requests." Id. ¶ 14. As the Court has previously determined when considering similar agency efforts in this case, "these efforts [together] show that FDA is exercising the due diligence necessary for" a stay. Feb. 4, 2025 Stay Order at 3; see Aug. 7, 2025 Stay Extension Order at 3; Feb. 12, 2026 Stay Extension Order at 4.

In short, the Court concludes that Defendants continue to face exceptional circumstances and to exercise due diligence and are thus entitled to a stay under Section 552(a)(6)(C)(i). But Defendants do not explain why FDA needs a twelve-month stay, rather than a six-month stay like those the Court has typically ordered in this case, to become "better positioned to evaluate its progress on processing the requests ahead of Plaintiff's FOIA request and when it will be able to respond to Plaintiff's request." Third Burk Decl. ¶ 20. And considering that FDA has completed its PHMPT I and II productions and the Court today issues its fourth stay, the Court has determined that the parties should propose a FOIA processing schedule before the stay expires. Accordingly, the Court will stay the case for six months and require the parties to file a joint status report before

the stay expires that proposes a schedule for FDA's processing of records responsive to ICAN's FOIA request in this case.

CONCLUSION

For these reasons, and upon consideration of [24] the parties' joint status report, and the entire record herein, it is hereby

ORDERED that this action is **STAYED** for six months, until April 14, 2027; and it is further

ORDERED that the parties shall file a joint status report by not later than April 13, 2027, providing an update on FDA's processing of FOIA requests that are ahead of ICAN's FOIA Request No. 2020-7162 in the Complex Queue and proposing a schedule for FDA's processing of that ICAN request.

SO ORDERED.

/s/
JOHN D. BATES
United States District Judge

Dated: October 23, 2026