IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY *Plaintiff*,	)	
v.	)	Civil Action No. 4:21-cv-01058-P
UNITED STATES FOOD AND DRUG ADMINISTRATION, *Defendant*.	)	

DEFENDANT'S BRIEF IN SUPPORT OF MOTION TO ALTER OR AMEND JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 59(e)

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I. INTRODUCTION

The U.S. Food and Drug Administration ("FDA") is undertaking unprecedented efforts to process federal records related to the development of COVID-19 vaccines under the Freedom of Information Act ("FOIA"). *See* Hr'g Tr. Jan. 28, 2022 at 9:19–23, ECF No. 58. Despite this extraordinary effort, however, FDA cannot meet the Court's most recent production deadline in this case while complying with the current production deadline in *PHMPT v. FDA*, No. 4:22-cv-915-P (N.D. Tex.) ("*PHMPT II*"). This Court has not considered the agency's ability to comply with such a deadline while working at full capacity to satisfy the production mandate already imposed in *PHMPT II*. Accordingly, for the reasons discussed below, Defendant FDA respectfully moves, under Federal Rule of Civil Procedure 59(e), to alter or amend the June 30, 2025 production deadline set forth in the Court's December 6, 2024 Order regarding the emergency use authorization ("EUA") file, *see* ECF No. 101 at 9, for the original Pfizer COVID-19 vaccine for individuals 16 years old and older. Defendant requests that the Court stay the June deadline until the conclusion of production in *PHMPT II*. Defendant further proposes that, within 14 days of completion of production in *PHMPT II*, the parties file a joint status report advising the Court and setting forth a proposed processing schedule for the responsive EUA file at a rate of 55,000 pages per month. *See* ECF No. 35; ECF No. 56 (modifying Jan. 2022 Order in part).

Alteration or amendment of the December 6, 2024 Order is warranted to correct clear error and/or prevent manifest injustice, given that the Court never considered the timing necessary to search for and process further records, the availability of agency resources, or the agency's other processing obligations and responsibilities under FOIA. A stay of the deadline is also appropriate because (1) "exceptional circumstance exist" given this Court's production Order in *PHMPT II*, the agency's other essential FOIA obligations, and the fact that the Court's December 6, 2024

Order in this case—*PHMPT v. FDA*, No. 4:22-cv-1058-P (N.D. Tex.) ("PHMPT I")—adds at least 589,600 pages to the agency's processing obligations through June 30, 2025, and (2) FDA "is exercising due diligence in responding to the [FOIA] request," given its extraordinary efforts to hire, train, and otherwise maximize efficiencies to comply with this Court's Orders in *PHMPT I* and *PHMPT II* and its other FOIA obligations, and the fact that it has a multi-track process for handling FOIA requests in which requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis. 5 U.S.C. § 552(a)(6)(C). Alternatively, the Court may grant the requested stay using "the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936).

The requested stay will help Defendant triage its limited resources while complying with this Court's substantial production Order in *PHMPT II*. The requested alteration of the June 30, 2025 deadline will also better ensure that, when the agency is able to turn to the responsive EUA file records, it can conduct a careful review to determine releasability. Nine courts have considered similar motions requesting litigation stays in light of this Court's prior production Orders in this case and in *PHMPT II* and have entered stays ranging from six months to eighteen months. No court has denied a stay. As in those cases, these circumstances justify a stay of the June 30, 2025 production deadline set forth in the Court's December 6, 2024 Order. In support of this motion, Defendant also includes a declaration from Suzann Burk ("Burk Decl."), Director of the Division of Disclosure and Oversight Management in FDA's Center for Biologics Evaluation and Research ("CBER").

II. BACKGROUND

This case concerns Plaintiff's FOIA Request for "[a]ll data and information for the Pfizer

Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." *See* Pl.'s FOIA Request, ECF No. 1-1 at 1. Plaintiff's FOIA Request further clarified that (a) "Pfizer Vaccine" meant "the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty . . . for individuals 16 years of age and older" and (b) its Request "includ[ed] but [was] not limited to all data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)." In January 2022, the Court ordered FDA to process approximately 55,000 pages of records responsive to this Request every 30 days, an order which the Court acknowledged to be "unprecedented" at the time. ECF No. 35 at 3; *see also* ECF No. 56. In compliance with the Court's Orders, the "FDA . . . produced some 1,200,874 pages of responsive records." ECF No. 101 at 2. After this processing was complete, the parties reached an impasse over whether FDA had reasonably understood the scope of Plaintiff's FOIA Request to seek only data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer-BioNTech Comirnaty vaccine *approved* for individuals 16 years of age and older. Plaintiff argued that the EUA file for Pfizer's COVID-19 vaccine *authorized* for individuals 16 years of age and older was also responsive to its Request. Summary judgment briefing to resolve the issue followed. *See* ECF Nos. 90–100. In its summary judgment briefing, Plaintiff requested a February 20, 2025 production deadline, to which FDA responded that such a deadline was not possible. *See* ECF No. 94 at 22; ECF No. 99, Ex A. ¶ 27. The parties did not otherwise address the time and resources that would be necessary to process further records in this case, nor was the Court updated on the substantial efforts the agency has taken to comply with the production mandate in *PHMPT II* as well as other essential FOIA obligations. On December 6, 2024, the Court granted Plaintiff's motion for summary judgment and ordered FDA to process the "responsive EUA file," by no later

than June 30, 2025. ECF No. 101 at 9.

Since January 2022, CBER's Access Litigation and Freedom of Information Branch ("ALFOI") has been working at full capacity to satisfy the productions ordered by this Court in *PHMPT I* and *PHMPT II*, as well as other essential FOIA obligations. Burk. Decl. ¶ 6 (App'x 002). Collectively, this Court's prior Orders in *PHMPT I* and *PHMPT II* have required ALFOI to process at least an average of 55,000 pages per month from March 2022 to June 2023; 90,000 to 110,000 pages per month from July 2023 to November 2023; and, starting in December 2023, at least 180,000 pages per month until June 2025. *See* Order at 1, *PHMPT I*, ECF No. 56, Feb. 2, 2022; Order at 1–2, *PHMPT II*, ECF No. 38, June 12, 2023. Due to the number of estimated pages left to produce in *PHMPT II*, however, ALFOI will need to produce an average of more than 230,000 pages per month to meet the Court's June 30, 2025 production deadline in that case. Burk Decl. ¶ 6 (App'x 003). As of January 2, 2025, between this case and *PHMPT II*, the Plaintiffs have received approximately 4.5 million pages of records related to COVID-19 vaccines, with at least 1.2 million pages of records still to be processed in *PHMPT II*. *Id.* ¶ 19 (App'x 010). These substantial productions have come alongside a backdrop of other increased workload obligations, including an increase in FOIA requests and FOIA litigation stemming, in large part, from requests related to FDA's work pertaining to the COVID-19 pandemic. *Id.* ¶ 6 (App'x 003); *see also id.* ¶¶ 15–18 (App'x 008–010). The Court's December 6, 2024 Order adds, at a minimum, 589,600 pages to ALFOI's processing obligations through June 30, 2025 in this case. *Id.* ¶ 6 (App'x 003).

As a result of the exceptional circumstances posed by this Court's production Orders in *PHMPT I* and *PHMPT II*, FDA and/or the U.S. Department of Health and Human Services ("HHS") have moved for eighteen-month stays in thirteen FOIA cases seeking CBER-maintained records. *Id.* ¶ 26 (App'x 014). Every court that has considered the stay motion has granted it in

whole or in part. *See Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378 (RC), ECF No. 28 (D.D.C. Oct. 13, 2023) (granting unopposed motion for eighteen-month stay); *Informed Consent Action Network ("ICAN") v. FDA*, Civ. A. No. 23-0219 (RBW), ECF No. 27 (D.D.C. Nov. 21, 2023) (vacating all pending deadlines and setting status conference in six months), ECF No. 29 (D.D.C. May 24, 2024) (extending stay, with status conference in six months), (Nov. 25, 2024) (minute order extending stay, with status conference in approximately seven months); *Children's Health Def. v. FDA*, Civ. A. No. 23-2316 (LLA) (D.D.C. Dec. 13, 2023) (minute order granting eighteen-month stay until further order of court, with status report in six months addressing need for further stay of proceedings), (Dec. 23, 2024) (minute order keeping stay in place until further order of the court); *Children's Health Def. v. FDA*, Civ. A. No. 23-0220 (RDM), 2024 WL 147851 (D.D.C. Jan. 12, 2024) (granting stay of six months, with joint status report in six months), (Oct. 24, 2024) (minute order recognizing "the unusual and extraordinary demands placed on the FDA" and FDA's hiring and training efforts and concluding "all that the Court can do is require the most expeditious processing of the request at issue, consistent with reality," so that FDA should "begin processing the responsive documents no later than August 9, 2026"); *Children's Health Def. v. CDC*, Civ. A. No. 23-0431 (TNM), 2024 WL 3521593, at *5–6 (D.D.C. July 24, 2024) (granting stay of six months, with status conference in six months to determine whether stay should be extended); *ICAN v. FDA*, Civ. A. 23-3675 (JMC) (D.D.C. Sept. 4, 2024) (minute order granting stay of six months, with joint status report in six months); *ICAN v. FDA*, Civ. A. No. 23-3282 (ABJ), ECF No. 23 (D.D.C. October 11, 2024) (granting stay of six months until March 14, 2025, with status report due on March 14, 2025 addressing need for further stay of proceedings); *John Solomon v. Dep't of Health & Hum. Servs.*, Civ. A. No. 24-0572 (RBW), ECF No. 25 (D.D.C. Oct. 25, 2024) (order granting stay until June 26, 2026, with a status

conference scheduled for July 8, 2025, to "apprise the Court of the status of this case"); *ICAN v. FDA*, Civ. A. No. 24-1761 (CJN), ECF No. 18 (D.D.C. Nov. 20, 2024) (granting stay for approximately 8 months, until July 21, 2025 with a status report on or before July 23, 2025). In a tenth case, the plaintiff voluntarily dismissed its suit without prejudice after the stay motion was filed. *See* Stip. of Dismissal Without Prejudice, *ICAN v. FDA*, Civ. A. No. 23-1508 (CKK), ECF No. 15 (D.D.C. Oct. 2, 2023). A motion for stay is pending in the other three cases. *See ICAN v. FDA*, Civ. A. No. 24-1555 (RCL), ECF No. 13 (D.D.C. Sept. 25, 2024) (stay motion filed); *ICAN v. FDA*, Civ. A. No. 24-1905 (JDB), ECF No. 14 (D.D.C. Oct. 25, 2024), (same); *ICAN v. FDA*, Civ. A. No. 24-1906 (CRC), ECF No. 16 (D.D.C. Nov. 4, 2024) (same); *see also* Burk. Decl. ¶ 26 (App'x 014–017).

FDA is exercising due diligence and has made, and continues to make, extraordinary efforts to hire, train, and otherwise maximize efficiencies to comply with this Court's Orders in *PHMPT I* and *PHMPT II* and FDA's other FOIA obligations. Among other things, ALFOI hired and trained contractors (approximately nine full-time and one part-time) to focus on processing records in this case, at an estimated cost of approximately $3.5 million through October 2023. Burk Decl. ¶ 19–20 (App'x 010–011). Because of *PHMPT II* and an increase in FOIA litigation, ALFOI also brought on board six new employees between June 2023 and December 2023, five new employees between January 2024 and May 2024, and three new employees between October 2024 and December 2024—all of whom are currently being trained. *Id.* ¶ 22 (App'x 011); *see also id.* ¶ 27 (App'x 017). However, it takes approximately two years for new staff to be fully trained. *Id.* ¶ 24 (App'x 012). The training process initially slows the pace of processing outstanding requests because more senior employees must review the new employees' work, often line-by-line and word-by-word, to ensure that records are being correctly reviewed for necessary

redactions. *Id.* (App'x 012–013). Thus, despite ALFOI's good-faith investment in increasing its future processing capacity by training new employees, its resources remain limited during this lengthy onboarding period. *Id.* (App'x 013).

Therefore, in spite of the agency's extraordinary efforts, it cannot concurrently process and produce the responsive EUA file as contemplated by the Court in its December 6, 2024 Order and *also* comply with the current production deadline in *PHMPT II*, absent a stay of the production deadline. *Id.* ¶ 34 (App'x 019–020).

III. LEGAL STANDARDS

District courts have considerable discretion to alter or amend a judgment under Rule 59(e). *See Edward H. Bohlin Co. v. Banning Co.*, 6 F.3d 350, 355 (5th Cir. 1993). Generally, the reasons for altering or amending a judgment pursuant to Rule 59(e) are an intervening change in controlling law, the availability of new evidence not previously available, or the need to correct a clear error or prevent manifest injustice. *See, e.g.*, *In re Benjamin Moore & Co.*, 318 F.3d 626, 629 (5th Cir. 2002). Courts are required to strike the proper balance between the need for finality and the need to render a just decision on the basis of "all the facts." *Jones v. Stephens*, 998 F. Supp. 2d 529, 536 (N.D. Tex. 2014) (quoting *Bohlin*, 6 F.3d at 355). Stays in FOIA cases may be granted under either 5 U.S.C. § 552(a)(6)(C) or *Landis*. Each is discussed in turn.

A. Legal Standard Under 5 U.S.C. § 552(a)(6)(C)(i)

Generally, an agency that has received a FOIA request is expected to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request." 5 U.S.C. § 552(a)(6)(A)(i). However, under Section 552(a)(6)(C)(i), "[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).

In *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), the D.C. Circuit explained that "exceptional circumstances" existed to justify a stay within the meaning of Section 552(a)(6)(C)(i) when "an agency . . . is deluged with a volume of [FOIA] requests for information vastly in excess of that anticipated by Congress" and "when the existing resources are inadequate to deal with the volume of such requests within the time limits" provided by FOIA. *Id.* at 616. The D.C. Circuit also found that the agency was exercising "due diligence" because it had a large staff, separated between complex and simple cases, and handled cases on a first-in, first-out system. *Id.* at 613. Congress subsequently amended FOIA to endorse the logic of *Open America*. *See Elec. Frontier Found. v. Dep't of Just.*, 517 F. Supp. 2d 111, 116–17 (D.D.C. 2007) (explaining the 1996 amendments to FOIA).

Exceptional circumstances exist where there is, for example, a substantial, unpredictable increase in the number of FOIA requests that an agency receives. *See id.* at 119 (finding "exceptional circumstances" when there was a one-third increase in FOIA requests and inadequate numbers of staff available to handle the increased volume); *Shapiro v. Dep't of Just.*, Civ. A. No. 12-313 (BAH), 2014 WL 12912625, at *2 (D.D.C. Dec. 8, 2014) (finding "exceptional circumstances" where a repeat plaintiff filed eighty-one FOIA requests with the agency totaling 375,000 pages and comprising six to seven percent of the agency's monthly intake, and the agency "could not reasonably have planned for a single citizen to consume such a vast quantity of the agency's FOIA resources"); *Eakin v. U.S. Dep't of Defense*, Civ. A. No. 16-972-RCL, 2017 WL 3301733, at *7–8 (W.D. Tex. Aug. 2, 2017) (granting *Open America* stay, where "[g]iven the sheer volume of plaintiff's request, and a large number of other requests the office must process,"

the agency's "resources are inadequate to process the request within the time limits set forth in [the] statute").

Exceptional circumstances also can be shown by an increase in FOIA litigation. For example, exceptional circumstances exist where "resources—and most notably, FOIA staff members—ha[d] been diverted to assist with multiple FOIA lawsuits, at least five of which are particularly resource-intensive and involve tens of thousands of documents." *Nat'l Sec. Archive v. SEC*, 770 F. Supp. 2d 6, 9 (D.D.C. 2011). A combination of increased FOIA requests and litigation can also demonstrate "exceptional circumstances." *Energy Future Coal. v. Off. of Mgmt. & Budget*, 200 F. Supp. 3d 154, 161–62 (D.D.C. 2016) (finding "exceptional circumstances" and granting six-month stay of FOIA proceedings where an agency had sixty-eight pending FOIA requests, twenty-seven of which predated plaintiffs' request, and was in litigation in two other FOIA cases).

When an agency demonstrates exceptional circumstances that rise above a predictable workload of requests, it needs to show due diligence to receive a stay but does not need to show that it is reducing the backlog of pending requests. *See* 5 U.S.C. § 552(a)(6)(C)(ii) (adding limits to "exceptional circumstances" that apply only when a delay results from a "predictable agency workload of requests," in which case an agency must show "reasonable progress in reducing its backlog of pending requests"); *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 60 (D.D.C. 2018) ("Because the court finds that exceptional circumstances exist based on the dramatic increase in FOIA requests and the agency's exercise of due diligence in responding to those requests, the court need not reach the question whether Defendant is making reasonable progress in reducing its backlog.").

An agency acts with due diligence when it processes requests on a first-in, first-out basis,

see, e.g., *Appleton v. FDA*, 254 F. Supp. 2d 6, 10 (D.D.C. 2003) (concluding that "the defendants have demonstrated good-faith efforts and due diligence in processing the plaintiff's request on a first-in, first-out basis"), or processes them in a "multi-track" system of "simple" requests, which are expedited, and "complex" requests, which take longer to process, *see Energy Future Coal.*, 200 F. Supp. 3d at 162 (finding that "[the agency] has exercised due diligence by processing Plaintiffs' FOIA request within [the agency's] 'multi-track' processing system," under which "[the agency] resolves 'simple' and 'expedited' requests in an expedited fashion, while [the agency] concurrently responds to 'complex requests' by making rolling productions"). An agency may also show due diligence by reorganizing its resources to better respond to increased FOIA requests, or by pursuing additional funding or employees, although the latter steps are not required. *Democracy Forward Found.*, 354 F. Supp. 3d at 62 (finding "due diligence" based on agency's efforts to reorganize staff and create complex and expedited queues in response to increased FOIA requests, even where agency did not seek additional funding for FOIA processing or increase the number of employees).

B. Inherent Authority to Stay Proceedings under *Landis*

An alternative ground for issuance of a FOIA litigation stay is a court's exercise of its inherent authority to control its docket. *Landis*, 299 U.S. at 254. "The power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Id.* To issue a *Landis* stay, a court balances competing interests, weighing the specific hardships to the parties and the interest in judicial economy. *See id.* at 255.

Courts have specifically applied *Landis* to grant stays in FOIA cases. *See, e.g.*, *Campaign for Accountability v. Dep't of Just.*, 280 F. Supp. 3d 112, 114–17 (D.D.C. 2017) (citing *Landis*

and granting stay in FOIA action to allow Office of Legal Counsel to evaluate the agency's position regarding refined claims in an amended complaint); *Children's Health Def. v. CDC*, Civ. A. No. 23-0431 (TNM), 2024 WL 3521593, at *5–6 (D.D.C. July 24, 2024) (granting stay pursuant to *Landis* to, among other things, *(i)* avoid adding to agency burden from extraordinary production order imposed by another court, *(ii)* prevent risk of interference with stayed cases involving the same documents, and *(iii)* maintain fairness to other requesters waiting in the queue longer than plaintiff); *Huddleston v. FBI*, Civ. A. No. 20-0447, 2021 WL 1837548, at *2 (E.D. Tex. May 7, 2021) (citing *Landis* to grant stay followed by production at "a standardized rate of 500 pages per month" due to "strained resources of their departments and significant volumes of other FOIA requests"); *see also Elec. Frontier Found. v. Off. of Dir. of Nat'l Intel.*, Civ. A. No. 08-1023, 2009 WL 773340, at *2–4 (N.D. Cal. Mar. 23, 2009) (granting *Landis* stay to plaintiff who requested time to review newly issued FOIA guidelines; defendant would not be prejudiced, and stay would further orderly course of justice).

IV. ARGUMENT

A. The Court Should Alter or Amend the December 6, 2024 Order by Granting the Requested Stay Under 5 U.S.C. § 552(a)(6)(C)(i) Because FDA Can Demonstrate "Exceptional Circumstances" and "Due Diligence."

This Court should stay the production deadline in its December 6, 2024 Order because FDA can show, under Section 552(a)(6)(C)(i): (i) "exceptional circumstances" based on this Court's unprecedented Orders requiring voluminous production in this case and *PHMPT II* and substantial increases in FOIA requests and litigation involving ALFOI; and (ii) "due diligence" based on the extraordinary efforts ALFOI took to comply with the *PHMPT I* 2022 Orders and has been taking to comply with the *PHMPT II* Order, including hiring and training new staff and contractors, reorganizing and triaging staff resources, and continuing to seek additional funding. As noted above, every court that has ruled on a motion for stay in a FOIA suit seeking CBER

records on similar grounds has granted the motion in whole or in part.

1. This Court's *PHMPT II* Order Requiring Production of at Least 180,000 Pages Per Month until June 30, 2025, and Other Increased Obligations, Constitute "Exceptional Circumstances."

FDA has been facing "exceptional circumstances." The concurrent court-ordered productions in this case and *PHMPT II* have involved approximately 5.7 million pages of COVID-19 vaccine-related records and collectively have required ALFOI to produce records at rates totaling 90,000 to 110,000 pages per month from July 2023 to November 2023 and at least 180,000 pages per month beginning in December 2023. *See* Burk Decl. ¶¶ 6, 19, 21 (App'x 002–003, 010–011). Throughout this time, ALFOI has faced an increase in FOIA requests and lawsuits. *See id.* ¶¶ 6, 15–18 (App'x 003, 008–010). These increases have further strained the agency's limited resources and ability to perform the requisite careful, line-by-line and word-by-word review of all records as required by law. *See id.* ¶¶ 7, 10, 33 (App'x 003, 006, 019) (noting line-by-line review process); *id.* ¶ 24 (App'x 012–013) (describing new-employee training process); Decl. of Suzann Burk ¶ 5, App'x in Support of Def.'s Brief in Advance of Scheduling Conference, ECF No. 23, Ex. A (describing ALFOI's litigation-related responsibilities).

To the government's knowledge, this Court's 2022 Orders in this case required the agency to process records at a rate that was many orders of magnitude greater than anything any agency had ever encountered in a FOIA order, and was soon surpassed by an even more extraordinary Order by this Court in *PHMPT II*. *Id.* ¶ 22 (App'x 011–012); *see ICAN v. FDA*, Civ. A. No. 23-3282 (ABJ) (D.D.C.), ECF No. 23 at 3 (Oct. 11, 2024 Order) ("[T]he [*PHMPT II* production] order from the Northern District of Texas bears no relationship to the FOIA orders ordinarily issued in this courthouse, even in cases of equal public importance."); Hr'g Tr. Jan. 28, 2022 at 9:19–23, ECF No. 58 (this Court stating that "not only is this unprecedented, but it appears to me the FDA is taking some unprecedented steps in order to comply"). Moving forward, to meet the

Court's June 2025 deadline in *PHMPT II*, ALFOI will need to produce an average of more than 230,000 pages per month. Burk Decl. ¶ 6 (App'x 003). The Court's December 6, 2024 Order in this case adds, at a minimum, 589,600 pages to ALFOI's processing obligations through June 2025—an additional burden that the agency cannot meet while concurrently complying with the Court's *PHMPT II* production Order. *Id.* ¶¶ 6, 29, 34 (App'x 003, 018–020).

This comes amidst a backdrop of other increased workload obligations, including an increase in FOIA requests and FOIA litigation, stemming, in large part, from requests related to FDA's work pertaining to the COVID-19 pandemic. *Id.* ¶ 6 (App'x 003). Before the 2022 production Orders in this case, ALFOI was able to keep its FOIA queues relatively low and stable with nine regular staff and one branch chief. *Id.* ¶ 15 (App'x 008). From fiscal years 2015 to 2018, the number of FOIA requests received by CBER each year ranged from 255 to 343, and the number of FOIA requests pending at the end of each year ranged from 39 to 54. *Id*. (App'x 008). The number and complexity of FOIA requests began to increase in FY 2019. *Id.* ¶ 16 (App'x 008). By FY 2021, CBER began to receive more than 500 requests annually, with 509 requests in FY 2021 and 633 requests in FY 2022. *Id*. (App'x 008). By the end of FY 2022, the number of pending FOIA requests grew to 532. *Id*. (App'x 009). By the end of FY 2023, although the number of FOIA requests received declined to 487, the number of requests closed also declined to 336, while the number of pending requests increased to 679. *Id*. (App'x 009).

Moreover, starting in FY 2020, FOIA suits added significantly to ALFOI's workload. *Id*. (App'x 008). Before FY 2020, few suits involving ALFOI were filed; today, it is involved in twenty active litigation cases, including this one. *Id.* ¶ 17 (App'x 009–010). The Burk Declaration provides two tables summarizing the trends related to the increases in ALFOI's FOIA workload obligations. *Id.* ¶¶ 15–16 (App'x 008–009); *see also id.* ¶ 17 (App'x 009–010). The data collected

as of the end of FY 2023 show that the number of pending FOIA requests has continued to grow under the strain of increased requests and increased FOIA litigation, which demands ALFOI's attention. *Id*. ¶ 16 (App'x 009); *see also* Burk Decl. ¶ 5, App'x in Support of Def.'s Brief in Advance of Scheduling Conference, ECF No. 23, Ex. A (describing ALFOI's litigation-related responsibilities). As of December 31, 2024, the number of pending FOIA requests increased to 844. *Id.* ¶ 18 (App'x 010).

In this case, the Court ordered FDA to produce records beginning in March 2022 at an average rate of 55,000 pages per month. *Id.* ¶ 20 (App'x 010). Given that the production rate ordered in this case far exceeded FOIA production rates typically ordered by courts (as acknowledged by this Court as well, Hr'g Tr. Jan. 28, 2022 at 9:19–23, ECF No. 58), the agency implemented immediate and sweeping organizational and work process changes including, among other things, hiring contractors and additional full-time employees at a substantial expense, reorganizing staff, and diverting resources from processing other FOIA matters. *Id.* (App'x 010–011).

While the agency's extraordinary efforts to marshal resources to comply with the *PHMPT I* Orders were ongoing, FDA was sued in *PHMPT II*. *Id.* ¶ 21 (App'x 011). In *PHMPT II*, this Court imposed an even more intense monthly production schedule. *See PHMPT II*, ECF No. 38. From July 2023 to November 2023, ALFOI was required to produce 90,000 to 110,000 pages per month in *PHMPT I* and *PHMPT II* collectively. *Id.* ¶ 21(A) (App'x 011). Then, beginning in December 2023, after initial production in this case had concluded, the agency has been required to produce 180,000 pages per month in *PHMPT II*. *Id.* ¶ 21(B) (App'x 011). Because of *PHMPT II* and an increase in FOIA litigation, the agency once again reallocated its staff, leaving only a handful of staff working on all non-*PHMPT* FOIA requests. *Id.* ¶ 22 (App'x 011). The agency

hired six new employees between June 2023 and December 2023, five new employees between January 2024 and May 2024, and three new employees between October and December 2024. *Id.* ¶ 22 (App'x 011). However, it takes approximately two years for new staff to be fully trained, and the training process initially slows the pace of processing outstanding requests because senior employees must review new employees' work to ensure records are being correctly reviewed for necessary redactions. *Id.* ¶¶ 24, 27 (App'x 012–013, 017). Even if agency production in *PHMPT II* had concluded, and new staff were available to process the responsive EUA file pursuant to this Court's December 6, 2024 Order in this case, many likely would not have the appropriate training to do so and would require close supervision. *Id.* ¶ 27 (App'x 017) (noting that CBER's entire Special Disclosure Unit staff, all of whom are assisting with the *PHMPT II* production, have less than two years training and require close supervision; half have six months or less).

This Court's large production Orders, along with the backdrop of substantially increased FOIA litigation and requests, far exceed a "predictable" agency workload and thus constitute the "exceptional circumstances" that justify a stay. *See Elec. Frontier Found.*, 517 F. Supp. 2d at 119 (finding "exceptional circumstances" because the agency established more than a "predictable" or "routine" backlog based on a one-third increase in FOIA requests and inadequate numbers of staff available to handle the increased volume).

Indeed, even prior to this Court's December 6, 2024 Order, several courts have already held that these circumstances—most notably, this Court's prior production Orders in this case and in *PHMPT II*—constitute "exceptional circumstances" justifying a stay. *See, e.g.*, *ICAN v. FDA*, Civ. A. No. 24-1761(CJN), ECF No. 18 at 2 (D.D.C.) (Nov. 20, 2024 Order) ("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."); *ICAN v. FDA*, Civ. A. No. 23-3282 (ABJ) (D.D.C.), ECF No. 23 at 4 (Oct. 11, 2024 Order) ("These unprecedented production orders and subsequent agency efforts to meet its FOIA obligations far exceed a 'predictable' agency workload and constitute the 'exceptional circumstances' and due diligence justifying a stay"); *ICAN v. FDA*, Civ. A. No. 23-3675 (JMC) (D.D.C.) (Sept. 4, 2024, Min. Order) ("FDA has shown both exceptional circumstances and due diligence justifying an *Open America* stay"); *Children's Health Def. v. FDA*, Civ. A. No. 23-2316 (LLA) (D.D.C.) (Dec. 13, 2023 Min. Order) ("FDA has shown both exceptional circumstances and due diligence"), (Dec. 23, 2024 Min. Order) (keeping stay in place based on a continued finding of exceptional circumstances and due diligence); *ICAN v. FDA*, Civ. A. No. 23-0219 (RBW) (D.D.C.), ECF No. 27 (Nov. 21, 2023 Mem. Op. & Order) (vacating all pending deadlines and setting conference in six months because FDA "has shown exceptional circumstances exist and that the agency . . . is exercising due diligence" in responding to plaintiff's FOIA request); *Children's Health Def. v. FDA*, Civ. A. No. 23-0220 (RDM), 2024 WL 147851, at *3 (D.D.C. Jan. 12, 2024) ("The unprecedented rate at which the *PHMPT* orders require the FDA to produce records is exceptional, and it is, if anything more overwhelming that the extraordinary increase in FOIA workloads that past decisions have found sufficient to warrant stays"); *John Solomon v. Dep't of Health & Hum. Servs.*, Civ. A. No. 24-0572 (RBW) (D.D.C.), ECF No. 25 (Oct. 25, 2024 Order) (granting stay because the agency "has 'show[n] exceptional circumstances exist and that the agency . . . is exercising due diligence").

2. FDA is Exercising "Due Diligence."

As described in the Burk Declaration, ALFOI has a multi-track process for handling FOIA requests, where 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 for processing on a first-in, first-out basis. Burk Decl. ¶ 8–9 (App'x 004–005). This alone is sufficient to show "due diligence." *Energy Future Coal.*, 200 F. Supp. 3d at 162 (finding "due diligence" based on a "multi-track" processing system separating "simple" and "complex" requests). But, as detailed below, FDA can demonstrate extraordinary efforts to comply with its production orders while continuing to process FOIA requests that far exceed what is necessary to show "due diligence."

To comply with the 2022 Orders in *PHMPT I*, ensure compliance with the current production Order in *PHMPT II*, and fulfill its other responsibilities stemming from increased FOIA requests and litigation, CBER's FOIA office has undertaken immediate and aggressive efforts to hire additional staff and contractors, seek funding, and reorganize its resources. Burk Decl. ¶¶ 20, 22–23, 26–27 (App'x 010–012, 014–017). As noted above, prior to this Court's first production Orders in this case, ALFOI consisted of nine staff supervised by one branch chief. *Id.* ¶ 15 (App'x 008). After this Court's 2022 production Orders, ALFOI made large-scale changes to its staff and work processes. Among other things, ALFOI hired contractors (nine full-time and one part-time) to focus on processing records for this case. *Id*. ¶ 20 (App'x 010). The estimated cost of contractors alone for processing records in *PHMPT I* totaled approximately $3.5 million through October 2023. *Id*. (App'x 011). Between February 2, 2022 and November 1, 2023, ALFOI was also able to assign nine full-time employees to focus primarily on the *PHMPT I* production, leaving a smaller team of six full-time employees to assume primary responsibility for all other FOIA requests. *Id.* (App'x 010).

When the initial *PHMPT I* production concluded in November 2023, ALFOI was required to ramp up to 180,000 pages per month in December 2023 for the *PHMPT II* production, although

it will need to produce an average of more than 230,000 pages per month to meet the Court's June 30, 2025 deadline in that case. *Id.* ¶ 21(B), (C) (App'x 011). Since the *PHMPT II* Order issued, ALFOI once again reallocated staffing and left only a handful of staff working on all other FOIA requests. *Id*. ¶ 22 (App'x 011). It also increased the number of full-time employees. *Id.* ¶¶ 22, 27 (App'x 011, 017). ALFOI brought on board six new employees between June–December 2023, five new employees in between January–May 2024, and three new employees between October-December 2024, all of whom are currently being trained. *Id*. ¶ 22 (App'x 011). Of these fourteen employees, twelve are part of the newly established Special Disclosure Units ("Units")—which are currently focused primarily on the *PHMPT II* matter—and two have been assigned to process FOIA requests unrelated to *PHMPT II* litigation. *Id*. (App'x 011).

CBER continues to carefully consider the number of employees and contractors needed for these productions, while ALFOI is working diligently to train additional staff who will be critical to ensuring that FDA can comply with the existing *PHMPT II* production Order going forward. *See id.* ¶¶ 23–24 (App'x 012–013). Determining the number of employees/contractors needed for these enormous productions while factoring in the availability of necessary financial resources, requires ongoing, complex discussions with entities within and outside CBER (particularly during a time of budgetary uncertainty). *Id*. (App'x 012).

Importantly, while CBER's hiring and ongoing training efforts demonstrate the agency's "due diligence" and good-faith investment to comply with production mandates by this Court and address the existing backlog of FOIA requests, its efforts have been limited by the lengthy ramp-up period for hiring new employees and training new employees and contractors. *Id.* ¶ 24 (App'x 012). Thus, even if CBER is awarded additional resources, receiving funds and hiring are merely the first steps in a labor-intensive process needed to onboard employees and contractors so that

they can contribute to the Branch's disclosure efforts. *Id.* (App'x 012). The process of advertising, recruiting, interviewing, and conducting administrative onboarding of new employees alone takes several months (assuming a qualified candidate is found). *Id*. (App'x 012). While new employees and contractors are in training, current staff must spend time partnering with them to provide training and oversight. *Id*. (App'x 012). Staff must review new employees and contractors' work to ensure that personal privacy, trade secrets, and other protected information is not inadvertently disclosed. *Id*. (App'x 012). All told, after onboarding, it takes approximately two years for an employee or contractor to be fully trained so that he or she can meaningfully contribute to the Branch's disclosure efforts. *Id*. (App'x 012); *see also id.* ¶ 27 (App'x 017).

CBER recently restructured its FOIA office creating new full-time employee positions and onboarding new employees. As of January 2025, the CBER has added three supervisory positions and thirteen staff level positions. *Id.* ¶ 27 (App'x 017). Two of the new supervisory positions head the newly formed Units, which consist of six staff positions each. *Id.* (App'x 017). Currently, a total of twelve staff have been onboarded and assigned to the Units, all of whom are relatively (or brand) new and are receiving training. *Id.* (App'x 017). All Unit employees are assisting with *PHMPT II* productions. *Id.* ¶¶ 3, 27 (App'x 002, 017).

The extraordinary efforts ALFOI has undertaken in significantly expanding its numbers of staff, training new employees, and reorganizing staff resources, all while complying with unprecedented production Orders and managing multi-track queues of FOIA requests, more than demonstrate the "due diligence" needed for a stay of the June 30, 2025 production deadline. *See supra* at 15–16 (citing multiple recent cases in which courts have granted a stay, finding that FDA is exercising due diligence).

B. *Landis* Also Supports the Court Altering or Amending the December 6, 2024 Order by Granting the Request to Stay.

This Court may also exercise its inherent, equitable authority to grant a stay of the June 30, 2025 production deadline under *Landis*. "[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis*, 299 U.S. at 254. This "calls for the exercise of judgment, which must weigh competing interests and maintain an even balance." *Id.* at 254–55. A stay is appropriate when the movant's need "overrides the injury to the party being stayed." *Belize Soc. Dev. Ltd. v. Gov't of Belize*, 668 F.3d 724, 732 (D.C. Cir. 2012) (cleaned up). Thus, courts consider: (1) the hardship imposed on the moving party if the litigation proceeds without a stay, (2) any prejudice to the non-movant in granting a stay, and (3) the interests of judicial economy. *See Brown v. Lumpkin*, Civ. A. No. 19-2301, 2021 WL 3847491, at *17 n.11 (N.D. Tex. Aug. 27, 2021). All three factors militate in favor of granting a stay here.

First, FDA will suffer serious hardship if the June 30, 2025 production deadline set forth in the Court's December 6, 2024 Order is not stayed. As described in the preceding sections and the Burk Declaration, the agency already is triaging its limited resources and working at full capacity to address the extraordinary workload brought on by *PHMPT II* and other essential obligations. The Court's December 6, 2024 Order adds, at a minimum, 589,600 pages to the agency's processing obligations through June 30, 2025. Burk Decl. ¶ 6 (App'x 003). The agency understands that Plaintiff wants to receive the remaining records responsive to its FOIA request as quickly as possible, and ALFOI is committed to processing the responsive EUA file as ordered by this Court. *Id.* ¶ 34 (App'x 019). However, given the substantial effect that this Court's Orders in this case and *PHMPT II* have had on ALFOI's workload since January 2022, the significant likelihood that ALFOI will be unable to comply with the current production deadline in *PHMPT*

II absent a stay, and the fairness to other FOIA requesters currently positioned ahead of Plaintiff's request (i.e. requests in the agency's Complex Track that preceded the FOIA request in this case), ALFOI cannot concurrently process and produce the responsive EUA file as contemplated by the Court in its December 6, 2024 Order and also meet the requirements of the Court's *PHMPT II* Order. *Id.* ¶ 34 (App'x 019–020).

Second, Plaintiff—who has already received approximately 4.5 million records in response to its FOIA Requests here and in *PHMPT II*, *id.* ¶ 19 (App'x 010)—will not be prejudiced by the requested stay. Indeed, the requested stay is necessary to allow the agency to meet this Court's existing and ongoing production Order in *PHMPT II*. As explained above, ALFOI cannot concurrently process and produce the responsive EUA file *and* satisfy the Court's Order in *PHMPT II*. Given the agency's limited bandwidth, Plaintiff would not be materially prejudiced by having the remaining processing of one of its FOIA requests stayed while the agency finishes processing another one of Plaintiff's FOIA requests, particularly given that both requests relate to COVID-19 vaccines. Moreover, even if prejudice to Plaintiff PHMPT were a possibility, it would not outweigh the hardship faced by FDA if a stay were not granted. *See Children's Health Def. v. CDC*, Civ. A. No. 23-0431 (TNM), 2024 WL 3521593, at *6 (D.D.C. July 24, 2024) ("If the Court denies a stay, . . . FDA "may be forced to violate a court-mandated processing order given the reality of its limited resources.").

Third, a stay will promote judicial economy by discouraging a further onslaught of FOIA litigation. *See id.* at *5–6 (granting *Landis* stay and explaining that "forcing FDA to move . . . documents to the head of the line would encourage every well-heeled FOIA requester to litigate for a fast pass, all to the detriment of every other requester in the queue").

C. FDA Must Exercise Due Care in its Processing of Potentially Responsive Records.

FDA cannot take shortcuts or simply release records to relieve a backlog or complete processing of a particularly burdensome request. To the contrary, as the Supreme Court emphasized, FOIA exemptions serve "important interests" and are "as much a part of FOIA's purposes and policies as the statute's disclosure requirement." *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 439 (2019). Here, FDA must take the time and have the resources necessary to carefully process potentially responsive records and determine whether any FOIA exemptions apply. FDA may need to protect privacy interests discussed in the records (*i.e.*, withhold personal identifiable information). Furthermore, FDA may need to protect proprietary information, such as trade secrets and confidential commercial information, under Exemption 4 that provides "private parties with sufficient assurances about the treatment of their proprietary information so they will cooperate in federal programs and supply the government with information vital to its work." *Argus Leader*, 139 S. Ct. at 2366; *see also* Burk Decl. ¶ 31 (App'x 018) (noting that ALFOI will need to re-engage with Pfizer to identify sections of the responsive EUA file that Pfizer believes do not contain any information subject to FOIA Exemption 4). FOIA requesters, through the collective burden of their voluminous requests that could overwhelm an agency's FOIA processing capabilities, should not be able to subvert the FOIA exemptions' "important interests." *Argus Leader*, 139 S. Ct. at 2366.

D. Alteration or Amendment of the December 6, 2024 Order is Appropriate to Correct Clear Error and/or Prevent Manifest Injustice.

Most fundamentally, in imposing the June 30, 2025 production deadline for the responsive EUA file in this case, this Court did not consider the timing necessary to search for and process further records, the availability of agency resources, nor the agency's other processing obligations and responsibilities under FOIA. *See supra* at 3. Instead, the parties briefed (and the Court was

asked to decide) whether FDA's search was adequate, particularly insofar as it excluded the EUA file. *See* ECF Nos. 90–101. Neither party briefed the feasibility of meeting a June 30, 2025 production deadline.

Additionally, as relayed above, FDA has taken, and continues to take, extraordinary efforts to comply with this Court's prior Orders in this case and in *PHMPT II*. *See supra* Part IV.A. During the period where CBER has been complying with this Court's aforementioned Orders, there have been substantial increases in FOIA requests and litigation for CBER records, and there are numerous FOIA requests in the Complex Track to process. *See supra* at 13–14. Several courts have recognized these realities and have stayed CBER-related FOIA litigations. *See supra* at 4–6, 15–16. In fact, as of November 15, 2024, there are 135 requests pending in the Complex Track that were received by CBER before Plaintiff's FOIA Request in this case.[1] Burk Decl. ¶ 32 (App'x 019). Echoing the agency's concern with fairness to other requesters, *see id.* ¶¶ 7, 34 (App'x 003, 019–020), at least one court has commented on this Court's mandated out-of-order processing, *see* Hr'g Tr. Oct. 4, 2024 *in Children's Health Def. v. FDA*, Civ. A. No. 23-0220 (RDM) (D.D.C.), at 18:10-19:5 (App'x 039–040) (court noting he has "been deferential to the judge in Texas" but stating "I want my order in place before his next one, if there is one coming, if it relates to FOIA requests that came before whatever FOIA requests . . . that came in later so they are all jumping the queue. . . . [C]omity runs two ways."). Strict fairness would dictate that Plaintiff's Request in this case wait its turn in the Complex Track; however, as a show of good faith, the agency here is merely requesting that the Court stagger (and not further compound) its outstanding production

[1] Among the 135 requests in the Complex Track ahead of PHMPT's Request in this case, are two requests that are the subject of litigation: *ICAN v. FDA*, Civ. A. No. 24-1761 (CJN) (D.D.C.) and *ICAN v. FDA*, Civ. A. No. 24-1905 (JDB) (D.D.C.). Burk Decl. ¶ 17 (App'x 009). In both cases, FDA has sought litigation stays. *Id.* ¶ 26 (App'x 016) (also noting that the court granted an approximately eight-month stay in Civ. A. No. 24-1761).

mandates in the two cases before it.

V. CONCLUSION

For the foregoing reasons, the Court should grant Defendant's Motion to Alter or Amend Judgment Pursuant to Federal Rule of Civil Procedure 59(e), such that the June 30, 2025 production deadline set forth in the Court's December 6, 2024 Order is stayed until the completion of production in *PHMPT v. FDA*, No. 4:22-cv-915-P (N.D. Tex.), and the Court should further order the parties to file a joint status report within 14 days of completion of production in *PHMPT II*, advising the Court and setting forth a proposed processing schedule at a rate of 55,000 pages per month for the responsive EUA file.

Dated: January 3, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2025, I electronically filed this document with the Clerk of the Court for the United States District Court for the Northern District of Texas by using the CM/ECF system. Counsel in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

/s/ Andrew F. Freidah
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