UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 23-0220 (RDM)

DEFENDANT'S REPLY IN SUPPORT OF ITS
MOTION FOR AN EIGHTEEN-MONTH STAY OF PROCEEDINGS

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Defendant United States Food and Drug Administration ("FDA") respectfully submits this Reply to Plaintiff's Opposition (ECF No. 19, "Pl. Opp.") to Defendant's Motion for an Eighteen-Month Stay of Proceedings (ECF No. 17).

PRELIMINARY STATEMENT

As explained in its Motion, FDA is entitled to a stay under *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), because orders in two cases brought by *Public Health & Medical Professionals for Transparency* imposed on FDA an overwhelming workload that it could not have predicted, and FDA is exercising due diligence in responding to those orders and the other substantial demands upon the agency. Plaintiff's response largely focuses on its belief that the data that it seeks might be interesting.

But the sole issue before the Court is whether FDA may receive a limited stay of these FOIA proceedings, during which time FDA will work at full capacity to meet extraordinary court-ordered productions and continue to process complex track queue requests received ahead of Plaintiff's request.[1] FDA moved for a stay because the two referenced court orders mandate that it produce approximately 5.7 million pages of records at a pace that is unprecedented in the history of FDA and, to its knowledge, any agency. *See Pub. Health & Med. Profs. for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex. Jan. 6, 2022), ECF No. 35 ("*PHMPT I*"); *Pub. Health & Med. Profs. for Transparency v. FDA*, Civ. A. No. 22-0915 (N.D. Tex. June 12, 2023), ECF No. 38

[1] FDA has filed similar motions to stay in the following cases: *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378 (D.D.C.) (RC) (unopposed motion for an eighteen-month stay granted on October 13, 2023); *Children's Health Def. v. FDA*, Civ. A. No. 23-2316 (D.D.C.) (TJK) motion for an eighteen-month stay pending); *Informed Consent Action Network v. FDA*, Civ. A. No. 23-0219 (D.D.C.) (RBW) (motion for an eighteen-month stay pending); *Informed Consent Action Network v. FDA*, Civ. A. No. 23-1508 (D.D.C.) (CKK) (case voluntarily dismissed after FDA filed a motion to stay for eighteen months).

("*PHMPT II*") (collectively, the "*PHMPT* orders"); *see also* Burk Decl. ¶ 7, ECF No. 17-2. Since the *PHMPT II* order was issued in June 2023, FDA has produced between 90,000 and 110,000 pages per month in *PHMPT I* and *PHMPT II*, collectively; beginning next month, FDA must produce at least 180,000 pages per month in *PHMPT II*. *See* Mem. in Supp. of FDA Mot. ("FDA Mem."), ECF No. 17-1 at 9; Burk Decl. ¶ 26, ECF No. 17-2.

Plaintiff does not dispute that the volume and rate of production ordered in *PHMPT II* is likely greater than any FOIA order in the history of this, or any, agency. The Opposition does not address the magnitude of the *PHMPT* orders at all. Instead, Plaintiff argues that these orders are not "exceptional circumstances" under 5 U.S.C. § 552(a)(6)(C) because of FDA's overall budget and FOIA resources. Regardless whether the *PHMPT* orders are considered in the context of the Center for Biologics Evaluation and Research's (the "Center") workload or FDA's overall FOIA workload, the unparalleled volume and production rate required by these orders constitute "exceptional circumstances." Moreover, as explained in the attached Declaration of Sarah Kotler, non-FOIA or non-Center resources do not affect FDA's need for this stay because those resources cannot be diverted from other important agency functions and cannot substitute for the specialized work performed by the Center's Access Litigation and Freedom of Information Branch (the "Branch"), which reviews and ultimately produces the Center's records. Kotler Decl. ¶¶ 15-17, attached hereto; *see also* Burk Decl. ¶ 12, ECF No. 17-2.

Plaintiff's arguments that FDA cannot show due diligence under 5 U.S.C. § 552(a)(6)(C), both generally and with respect to its specific request, also fall short. First, Plaintiff fails to credit appropriately FDA's extraordinary efforts to hire and train new employees since the *PHMPT I* production order issued, claiming they are insufficient to show due diligence under 5 U.S.C. § 552(a)(6)(C). *See* Pl. Opp. at 20. As detailed in the Burk Declaration (¶¶ 24-25, 28-30),

however, FDA's efforts to add to and maximize Branch resources go far beyond what is necessary to show due diligence. Second, Plaintiff incorrectly argues that FDA cannot show due diligence because FDA's requested stay would remove Plaintiff's FOIA request from the FOIA queue entirely and allow other requests to move ahead of it. Pl. Opp. at 23. But FDA does not seek to remove Plaintiff's request from the queue. As detailed in the Supplemental Declaration of Suzann Burk ("Supp. Burk Decl."), several hundred requests are waiting in the queue in front of Plaintiff's request. *See* Supp. Burk Decl. ¶ 11, attached hereto (explaining that, as of October 18, 2023, there were approximately 368 requests ahead of Plaintiff's request in the Complex Track). If the Court grants the stay, FDA will continue to process the requests received ahead of Plaintiff's request and, if those requests are processed before the stay ends, FDA will then process Plaintiff's request. *Id.* ¶ 12. Thus, FDA is not seeking to remove Plaintiff from its place in the queue. It is Plaintiff that seeks to remove itself from the queue and leapfrog other requesters already in line.

Finally, Plaintiff's arguments against a stay under *Landis v. North American Co.*, 299 U.S. 248, 255 (1936), fail. Again, Plaintiff ignores the unprecedented burdens that *PHMPT I* and *PHMPT II* put on the Center's (and FDA's) resources and fails to articulate a harm that it might suffer from receiving records after a stay that would overcome the showing of harm that FDA would suffer without a stay. As previously noted, FDA and the Centers for Disease Control and Prevention ("CDC") have made publicly available substantial information on the risks associated with COVID-19 vaccines. *See* FDA Mem. at 15-16. The additional information sought by Plaintiff, however, is merely one preliminary piece of an overall risk assessment. *Cf.* Nair Decl. ¶¶ 7, 14, *Informed Consent Action Network v. FDA*, Civ. A. No. 22-3572 (D.D.C. July 13, 2023) (CKK), ECF No. 21-5 (discussing the preliminary nature of data and the numerous additional analyses performed to evaluate vaccine risks).

ARGUMENT

I. An Eighteen-Month Stay Under 5 U.S.C. § 552(a)(6)(C)(i) Is Warranted Because FDA Has Demonstrated "Exceptional Circumstances" and "Due Diligence."

This Court should grant FDA's requested stay under Section 552(a)(6)(C)(i) because FDA has shown (1) "exceptional circumstances," based on the court orders requiring extraordinary productions in *PHMPT I* and *PHMPT II* and significant increases in FOIA requests and litigation involving the Branch; and (2) "due diligence," based on the remarkable efforts the Branch is taking to comply with these court orders, including hiring and training new staff and contractors, reorganizing and triaging staff resources, and continuing to seek additional funding. As explained below, Plaintiff's arguments to the contrary fall short.

A. The Court-Ordered Productions Totaling 90,000 to 180,000 Pages Per Month and Other Increased Obligations Constitute "Exceptional Circumstances."

If the historic, expedited production schedules in *PHMPT I* and *PHMPT II* do not constitute exceptional circumstances, nothing does. As the Burk Declaration explains (¶ 26), the production rate ordered in *PHMPT II* is, to FDA's knowledge, "many orders of magnitude greater than anything any agency has ever encountered in a FOIA order." Beginning in approximately one month—December 2023—FDA must produce a minimum of 180,000 pages per month in *PHMPT II*—more than triple the 55,000 pages per month that it was required to produce in *PHMPT I*. Plaintiff does not dispute this and ignores the magnitude of the required production.

Plaintiff insinuates that the breathtaking orders in *PHMPT I* and *PHMPT II* are not extraordinary because FDA's overall budget and resources are greater than that of the Branch alone. *See* Pl. Opp. at 3, 28-29. However, Plaintiff does not cite any case law under Section 552(a)(6)(C)(i) that precludes a court from considering the workload and resources of the relevant agency FOIA office when determining whether a stay under FOIA is warranted. Indeed, when

considering whether an agency has shown "exceptional circumstances" under Section 552(a)(6)(C)(i), it is appropriate for a court to frame its discussion around the burdens facing specific agency components. In *Judicial Watch, Inc. v. U.S. National Archives & Records Administration*, Civ. A. No. 07-1267, 2008 WL 11516011, at *1 (D.D.C. May 20, 2008) (JR), the Court focused on the workload burdens facing the specific agency component (the Clinton Library) in possession of the requested records when granting a stay based on "exceptional circumstances." *Id.* (concluding that a one-year *Open America* stay was warranted because, among other things, the Clinton Presidential Library had received 336 FOIA requests in a year, which was substantially more than the number of requests received by other presidential library components of the agency). Moreover, Plaintiff's focus on the overall budget and resources of the entire agency when demanding a preferred FOIA response schedule wrongly suggests that the agency must prioritize its record response role above its core functions. Of course, the FDA serves a vital role in protecting public health, and suggestions that even greater resources should be reallocated from those essential duties disregard the importance of FDA carrying out its core missions.

Similarly, when determining what a "reasonable" processing schedule looks like under 5 U.S.C. § 552(a)(6)(E)(iii), this Court has focused on the specific workload and resources of the FDA FOIA office assigned to the request at issue. *See Harrington v. FDA*, 581 F. Supp. 3d 145, 150-51 (D.D.C. 2022) (finding that FDA's proposed production schedule, which included a pause in processing one of plaintiff's FOIA requests, was reasonable given the plaintiff's outsize consumption of most of the FOIA resources for FDA's Center for Veterinary Medicine, the small size of the Center for Veterinary Medicine's FOIA staff, and the Center for Veterinary Medicine's FOIA backlog). In determining a reasonable processing schedule, this Court has focused on the workload of the specific agency FOIA component even though Section 552(a)(6)(E)(iii), like

Section 552(a)(6)(C)(i), speaks in terms of the "agency" and not a component. This makes sense because FDA is too large and decentralized for its resources to be considered interchangeable.

It would be manifestly inefficient to re-direct resources to the Center, as the Kotler Declaration explains. *See* Kotler Decl. ¶¶ 15-17. At a broad level, FDA generally cannot reallocate staff from non-FOIA functions because, with rare exceptions for short-term details, performing disclosure reviews is a specialized skill that requires training and expertise that most FDA staff do not have. *Id*. ¶ 16. Obviously 5 U.S.C. § 552(a)(6)(C)(i) does not contemplate pulling staff away from, for example, reviewing a cancer treatment application or conducting a counterfeit drug investigation to perform FOIA work for which staff would be untrained and unqualified. *See id*.; *see also* Burk Decl. ¶ 30 ("[I]t takes approximately two years for an employee to be fully trained so they can meaningfully contribute to ALFOI's disclosure efforts."). Disclosure staff outside the Center are also not interchangeable with Center disclosure reviewers, given that each component, including the Center, has its own disclosure regulations (*e.g.,* 21 C.F.R. §§ 601.50, 601.51), and reviewers from each component are trained to review the types of information regularly generated within their component. Kotler Decl. ¶ 17. Thus, a FOIA reviewer in the Center for Tobacco Products will not be trained in, or have familiarity with, reviewing a biologics license application or a vaccine-related record, whereas a Center FOIA reviewer would. *Id*.

Moreover, other FDA components' disclosure staff are already over-extended with their own disclosure duties, which also involve products and issues important to public health. Kotler Decl. ¶ 11. Although the number of FOIA requests submitted to FDA overall briefly decreased at the outset of the COVID-19 pandemic, the number of FOIA requests has increased in recent years, as has requests' complexity and the amount of ensuing FOIA litigation. *Id*. ¶¶ 9-10. In fiscal year 2023, FDA received approximately 10,396 new FOIA requests—an eleven percent increase from

fiscal year 2022 (9,333 requests received). *Id*. ¶ 10. FDA's resources to hire additional FOIA staff, both generally and in the Center, are limited because FOIA is an unfunded mandate—that is, it is not a separate "line item" category in FDA legislative appropriations. *Id.* ¶ 14. Thus, FOIA operations must be funded from general budgetary appropriations, which are also used to fund critical needs across FDA ranging from ensuring that the human food supply is safe (including modernization of the country's infant formula supply chain), to curbing unlawful marketing of tobacco products targeted at youth, to mitigating the harms associated with the prescription opioid epidemic. *Id*. (citing FDA, *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, https://www.fda.gov/media/166182/download?attachment (last accessed Oct. 30, 2023).

Importantly, regardless whether the *PHMPT* orders (and, in particular, *PHMPT II*'s requirement to produce 180,000 pages per month beginning in December 2023) are considered in the context of the Branch's workload or FDA's overall FOIA workload, they constitute "exceptional circumstances." Neither the Branch nor FDA has ever faced a court order requiring production approaching the volume and rate required by *PHMPT II*. The Branch is currently working at full capacity to meet both *PHMPT* orders and will need every resource available to it to be able to meet the increased production rate in *PHMPT II* beginning next month. Burk Decl. ¶ 31. While FDA has increased the number of staff and contractors working with the Branch and continues to aggressively recruit and hire new employees, increases in funding and hiring are only the first steps in a lengthy, labor-intensive process to train new employees to review these sensitive, highly technical records. *See id.* ¶ 30; Kotler Decl. ¶ 18.

Second, Plaintiff argues that the Branch's current workload is predictable, not exceptional, because (1) the Branch has received an increasing number of FOIA requests and lawsuits over the

past several years and (2) FDA should have predicted public interest in records related to COVID-19 vaccines. [2] *See* Pl. Opp. at 25-27. Again, Plaintiff's arguments require the Court to ignore the magnitude of the productions required by the *PHMPT* orders. The increasing requests actually counsel in favor of a stay. As FDA previously described, the backdrop of increasing FOIA requests and litigation in recent years has exacerbated the burdens of the *PHMPT* orders. Burk Decl. ¶¶ 18-22. Contrary to Plaintiff's argument, the increasing trend in the numbers of FOIA requests alone did not make "predictable" a court order requiring production at a previously unheard-of rate of 55,000 pages per month. At a January 2022 hearing in *PHMPT I*, government counsel told the court that the *PHMPT I* order was a "magnitude of two over the single largest [order] that's ever been recorded." *Pub. Health & Med. Profs. for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex. Feb. 7, 2022), ECF No. 58 at 8:24-25, 9:1-23 (Tr. of Jan. 2022 Hrg.). The *PHMPT I* court called its own order "unprecedented." *Id.* at 9:19-24. And that order, in turn, did not make the later 180,000 pages-per-month rate ordered in *PHMPT II* part of a "predictable" workload.

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[2] Plaintiff incorrectly states that FDA's regulation at 21 C.F.R. § 601.51(e) also provides "notice" that, when FDA approves a vaccine, licensing information "must be disclosed quickly and as a matter of course." Pl. Opp. at 26. This statement misrepresents the language of the regulation. Section 601.51 outlines how FDA treats information in a biological product file throughout the "lifecycle" of the application to which the biological product file corresponds. After a license for a biological product has been issued, section 601.51(e) provides that several enumerated categories of information within the biological product file lose their regulatory confidentiality and become "immediately available for public disclosure." 21 C.F.R. § 601.51(e)(1)-(8). Under this provision, the specified categories of information lose their across-the-board confidentiality protections, such that they are now available for public disclosure, upon request, pursuant to FOIA. The provision, however, does not require the immediate publication of such information. Moreover, as with any other agency record to be processed under FOIA, records that may include information listed in Section 601.51(e) must be carefully reviewed to determine whether one or more FOIA exemptions apply. Section 601.51(e) itself limits disclosure of several types of information if they fall within certain categories protected by FDA's regulations. *See* 21 C.F.R. §§ 601.51(e)(2), (3), (5), (6), (7).

Finally, FDA anticipated public interest in the COVID-19 vaccines. Thus, it affirmatively made great amounts of information about the vaccines available to the public on its website. *See* FDA Mem. at 15-16. In turn, FDA's affirmative disclosures made it less predictable that FDA would face the blanket demands for massive amounts of additional information made in *PHMPT\ I* and *PHMPT II*.

Not only does Plaintiff's argument not account for actual circumstances, Plaintiff's argument, if adopted, would make it effectively impossible for agencies to prove "exceptional circumstances." It will always be possible, as here, for FOIA requesters to point to some agency action they say makes their requests foreseeable.

Plaintiff also concludes, based on the numbers of additional staff and contractors hired for the Branch since the beginning of *PHMPT I*, that the Center has sufficient resources to manage all its FOIA obligations without a stay. *See* Pl. Opp. at 28-29. Plaintiff's conjecture is refuted by the activities of the staff actually working on these requests. *See* Burk Decl. ¶¶ 24, 28-31 (noting that a "small team of six FTEs . . . assume[d] primary responsibilities for all other FOIA requests" before *PHMPT II* came into effect); *see also Democracy Forward Found. V. Dep't of Just.*, 354 F. Supp. 3d 55, 59 (D.D.C. 2018) ("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.'" (quoting *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991))). Among other things, Plaintiff suggests that the end of the *PHMPT I* production in November 2023 will free up resources (Pl. Opp. at 29), but this ignores that the end of that production will be followed in December 2023 by the beginning of another, significantly burdensome production obligation—namely, the monthly 180,000-page productions for *PHMPT II* that is, more than triple the production rate ordered in *PHMPT I*.

In seeking a stay here, Defendant considered several factors, as it did for all pending litigation cases involving the Center, such as the legal/procedural posture of the case, whether FDA had already agreed to a production schedule approved by a court, whether production in a particular case was nearly complete, and the extent to which the requests would continue to require the Center's FOIA resources. Supp. Burk Decl. ¶ 7. So far, Defendant has sought stays in five cases (including this one) and continues to evaluate all-new Center FOIA litigation cases as potential stay candidates. *Id*. ¶ 8 (summarizing the status of cases in which FDA has so far sought a stay and noting that FDA's unopposed motion for an eighteen-month stay has been granted in *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378 (D.D.C. Oct. 13, 2023) (RC), ECF No. 28). Thus, Defendant has sought five nearly identical stays so far, of which two share the same plaintiff. That a third case "overlaps" with one of Plaintiff's requests (Pl. Opp. at 33-34) shows only that FDA looks to the nature of the request and not the identity of the requester when determining whether to seek a stay.

In sum, the unprecedented *PHMPT* orders, along with the backdrop of substantially increased FOIA litigation and requests, far exceed a "predictable" agency workload and thus constitute the "exceptional circumstances" needed to justify a stay under Section 552(a)(6)(C)(i). *See* FDA Mem. at 9-11.

B. FDA is Exercising "Due Diligence."

As described in the Burk Declaration (¶ 12) and Supplemental Burk Declaration (¶ 4), the Branch has a multi-track process for handling FOIA requests, whereby 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. Plaintiff does not dispute that this process alone is sufficient to show "due diligence." *See* Pl. Opp. at 23; *see also* FDA Mem. at 12 (citing *Energy Future Coal. V. OMB*, 200 F. Supp. 3d 154, 162 (D.D.C.

2016) (finding "due diligence" based on a "multi-track" processing system separating "simple" and "complex" requests)). Beyond that, FDA's extraordinary efforts to comply with court-ordered productions while continuing work on other FOIA requests far exceed what is necessary to show "due diligence." *See* FDA Mem. at 12-14 (describing the Branch's large-scale changes to its staff and work processes and substantial monetary resources dedicated to its efforts). Plaintiff does not refute that a multi-track processing system alone is sufficient to show due diligence but instead argues that FDA is not exercising "due diligence" based on Plaintiff's misunderstandings regarding the Branch's FOIA queues, the position of Plaintiff's request in the queue, and the effect of a stay on the request's position in the queue. *See* Pl. Opp. at 23.

First, as noted above, Plaintiff incorrectly argues that FDA's motion would remove Plaintiff's request from the queue, thereby departing from FDA's typical first-in, first-out practices. Pl. Opp. at 23; *see supra* at 3. To the contrary, Plaintiff's request retains its position in the queue regardless whether FDA's motion is granted. Although most Branch resources are currently being used to satisfy court-ordered productions, a handful of staff continue to process FOIA requests in the six queues, and those requests are assigned to reviewers for processing on a first-in, first-out basis. Supp. Burk Decl. ¶ 5. When a pending FOIA request becomes the subject of litigation, the typical first-in, first-out process may be affected—for instance, if a court orders that a request be processed on a specific timeline or orders the parties to confer and attempt to reach agreement on a production schedule, then a litigated request may end up effectively "jumping" the queue. *Id*. ¶ 6. But in the absence of a court order or court-filed processing agreement between parties, FOIA requests that are in litigation remain in their original position in their assigned FOIA queue and are not removed from that position. *Id*.

Thus, if a FOIA request that was in litigation came to the front of its queue (through the typical first-in, first-out process), the Branch would not "skip" the request simply because it was the subject of litigation. Supp. Burk Decl. ¶ 6. As of October 18, 2023, there are approximately 368 requests received before Plaintiff's request in the Complex Track that are awaiting processing. *Id*. ¶ 11. If a stay is granted in this case, Plaintiff's request will not be removed from its place in the Complex Track. *Id*. ¶ 12. If the approximately 368 requests ahead of Plaintiff's are processed before a stay is lifted in this case, the Court will be notified, and the Branch will begin processing Plaintiff's request. Therefore, given that the Branch is continuing to assign requests in this queue for processing on a generally first-in, first-out basis, working on requests in that queue as much as it can while balancing its enormous court-ordered production workload, and planning to process Plaintiff's request as soon as it comes up in the queue, FDA has shown due diligence, both generally and with respect to Plaintiff's request.

Plaintiff nonetheless argues that FDA has not shown due diligence because FDA identified the approximately 150 potentially responsive records that Plaintiff claims are easy to review. Pl. Opp. at 29. Plaintiff asserts that the records, if determined to be responsive, will not need to be redacted because they (purportedly) do not contain any information that is exempt from disclosure. *Id.* Plaintiff's speculation is no answer to FDA's showing.

As with any FOIA review, the Branch will need to conduct a line-by-line review of the responsive records to identify information that is protected from disclosure under FOIA, redact all exempt information, perform a quality control review, and prepare the records for disclosure, a process most efficiently conducted at the end of a records search. *See* Supp. Burk Decl. ¶¶ 13, 17; FDA Mem. at 5. For example, characterizing information in the records as "data" does not shed light on whether any or all of it is exempt. VAERS "data" is not just a running tally of objective

events. Because the data "derive from a complex set of judgments," it may be predecisional. *Quarles v. Dep't of Navy*, 893 F.2d 390 (D.C. Cir. 1990). As described in FDA's briefs and declarations, the Branch simply lacks the resources to finish the search and conduct the necessary review at this time.[3] Further, the review and release of any already identified, potentially responsive records and release of those that are responsive and non-exempt will not end the litigation, as the search has not yet been completed.

Finally, Plaintiff's argument that FDA should be required to divert resources from FOIA offices in other centers to show due diligence (Pl. Opp. at 28-30) also fails. As described in the Kotler Declaration, disclosure staff from other centers are not interchangeable with the Center's FOIA reviewers and, in any event, disclosure officers in other offices are fully committed to their own workloads. Kotler Decl. ¶ 17. As Plaintiff acknowledges, FDA's overall FOIA backlog has grown in recent years, with 4,188 requests pending at the end of fiscal year 2022. *See* Pl. Opp. at 17. While FDA has taken concrete steps to reduce backlogs and improve processing time throughout its FOIA offices through hiring, training, and process changes, its resources to hire additional FOIA staff are limited. *See* Kotler Decl. ¶¶ 13-14.

Plaintiff's arguments thus fail to undermine FDA's showing that it has demonstrated the "due diligence" needed for a stay under Section 552(a)(6)(C)(i). *See* FDA Mem. at 12-14.

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[3] Even if it could divert staff from work on *PHMPT II* (which it cannot), it would be a highly inefficient use of resources to review records when the search for responsive records has not been completed. *See* Supp. Burk Decl. ¶ 13. Waiting until the search is completed will typically enable the Branch to de-duplicate records, minimizing review time. *Id*. And importantly, redactions would be made in the context of a complete universe of responsive documents, which will ensure consistency and reviewer understanding of the context of the information under review. *Id*.

C. FDA Does Not Need to Show a Reduction in its FOIA Backlog Because It Has Established "Exceptional Circumstances" Beyond a "Predictable" Workload and "Due Diligence."

As Plaintiff notes, "exceptional circumstances" includes a delay that results from predictable agency workload if the agency can show reasonable progress in reducing its FOIA backlog. *See* Pl. Opp. 24. However, Plaintiff wrongly asserts that FDA's workload is predictable. Pl. Opp. at 25. To the extent that Plaintiff is implying that FDA is required to show a reduction in its FOIA backlog to meet the "exceptional circumstances" standard, Plaintiff is incorrect. As explained above and in FDA's Memorandum, FDA has established "exceptional circumstances" exceeding a "predictable" workload and has shown "due diligence" under Section 552(a)(6)(C)(i), thus FDA does not need to prove a reduction in its FOIA backlog. FDA Mem. at 6-7 (citing 5 U.S.C. § 552(a)(6)(C)(ii) and *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 60 (D.D.C. 2018)).

In any event, the number of FOIA requests that are pending does not, by itself, give the full picture regarding whether an agency is making reasonable progress in reducing its pending workload. For example, in *PHMPT I* and *PHMPT II*, the Branch is making monthly productions that, despite responding only to a handful of FOIA requests (i.e., the requests made by Plaintiffs in *PHMPT I* and *PHMPT II*), involve a monthly volume of records that may be higher than what tens (or even hundreds) of other FOIA requests in the backlog collectively involve. Thus, although FDA need not show that it is making reasonable progress in reducing its FOIA backlog, its production of hundreds of thousands of pages per month unquestionably reflects such progress.

II. Alternatively, the Court Should Exercise Its Inherent Authority to Stay This Action Under *Landis*.

Plaintiff's arguments against a *Landis* stay are insufficient to overcome FDA's showing that a stay is warranted here. Under *Landis*, 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) (internal quotation marks omitted). FDA has shown that it will suffer serious hardship absent a stay, and a stay will not harm Plaintiff. FDA Mem. at 14-16. FDA simply lacks the resources to search for, review, and release relevant documents. Similarly, a stay will obviate the need for court oversight at a time when FDA cannot agree to a production schedule, thereby promoting judicial economy. *Id*. at 16.

Plaintiff has failed to articulate a specific need for or urgency concerning these records sufficient to demonstrate that Plaintiff will be injured if the Court grants a stay. Plaintiff's claims that the public will be denied access to critical safety data about COVID-19 vaccines that would shed light on adverse events, and that possession of Empirical Bayesian analyses of COVID-19 vaccine-related data will contribute significantly to the public's understanding of the government's vaccine safety programs, are unfounded.

FDA has already made a substantial amount of COVID-19 vaccine-related adverse event information available through its public-facing website and previous FOIA disclosures. *See* FDA Mem. at 15-16. Similarly, CDC provides COVID-19 vaccine-related information on its website and has released adverse event data to Plaintiff. *See id.*; *see also* Pl. Opp. at 7. For example, the public can currently access the Action Packages for both the Comirnaty and Spikevax vaccines, which include Clinical Review Memoranda (providing information about clinical trial safety and efficacy and risk-benefit considerations and recommendations, among other things), Statistical Review memoranda, Package Inserts, Approval Letters, and the Summary Basis for Regulatory Action, as well as millions of pages of records relating to the biological license application file for both vaccines, including all safety and effectiveness data, reaction reports, product experience reports, consumer complaints, and other similar data and information. *See* 21 C.F.R. § 601.51(e);

FDA Mem. at 15-16 (describing information already disclosed to the public). Immediate access to the information Plaintiff seeks will not supplant or add significant value to the voluminous information FDA and CDC already have made available to the public, nor is such immediate access feasible given current resource constraints on the Center.

Dr. Narayan Nair, the Director of the Division of Pharmacovigilance in the Center, discussed the role Vaccine Adverse Event Reporting System and Empirical Bayesian data mining play in the post-market safety surveillance of COVID-19 vaccines in a declaration that was filed in another recent FOIA matter brought by Plaintiff. *See* Nair Decl. In his declaration, Nair explained that the Vaccine Adverse Event Reporting System, its data, and analyses of the same "represent one preliminary piece of [the Center's] overall assessment to determine whether a COVID-19 vaccine presents a higher risk of death to the population at large than is already understood by experts and has been communicated to the general public." *Id.* ¶ 14. Experts engage in numerous additional analyses "before they can conclude that a COVID-19 vaccine presents a higher risk of death than is currently understood by experts and has been communicated to the general public" and "before recommending regulatory action to address a newly understood risk or an increase in the risk of an adverse event like death." *Id*. ¶¶ 12, 13. In other words, Empirical Bayesian data mining of COVID-19 vaccine-related data from the Vaccine Adverse Event Reporting System does not, by itself, reveal the risk of adverse events associated with COVID-19 vaccines or the inner workings of FDA's vaccine safety surveillance program. Therefore, even if Plaintiff were now to receive any non-exempt responsive information in the records it seeks, it could not reliably draw conclusions from that information about the safety of COVID-19 vaccines or FDA's efforts to effectively monitor, analyze, and respond to adverse event reports submitted

to the Vaccine Adverse Event Reporting System, which thus ameliorates the claimed urgency of Plaintiff's need for these records. *See, e.g.*, *id.* ¶ 14.

Finally, Plaintiff argues that FDA will not suffer hardship without a stay because "[b]eing required to follow the law and to process [the] FOIA request" does not constitute hardship. Pl. Opp. at 36. Indeed, Plaintiff misunderstands the hardship to FDA, *i.e.*, the burden on the Branch from having to respond to Plaintiff's FOIA request while its contractors and regular staff are completely occupied with processing *PHMPT II* records after *PHMPT I* ends. Indeed, the end of *PHMPT I* does not represent a decrease in the Branch's FOIA workload but a significant increase, as the *PHMPT II* production ramps up to 180,000 pages per month. *See* Burk Decl. ¶ 26 (summarizing the *PHMPT II* production schedule, which increases the Branch's production requirement in the month following the completion of processing and production for *PHMPT I*); *id.* ¶¶ 28-30 (explaining the Branch's efforts to maximize its resources and the limitations of hiring/funding); *id.* ¶ 31 (stating that the Branch does not have the bandwidth to concurrently produce records in this litigation while meeting its court-ordered obligations). Regardless of the total amount of resources needed to complete production in this case, the Branch simply does not have any extra resources to spare, and that is why it is seeking a stay of this case and other cases where appropriate. After an eighteen-month stay, the Branch will be better situated to confer with Plaintiff about a reasonable production schedule for any responsive records in this case, and during these eighteen months, FDA's proposed status reports (at six-month intervals) are intended to provide Plaintiff and the Court with reasonable updates regarding FDA's progress in *PHMPT II*.

Accordingly, this Court should exercise its inherent authority to stay this action under *Landis*.

CONCLUSION

For the foregoing reasons and the reasons provided in FDA's Memorandum, FDA respectfully requests that this Court grant an eighteen-month stay in this case.

Date: November 7, 2023
Washington, DC

Respectfully submitted,

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