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)

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

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INTRODUCTION

Defendant United States Food and Drug Administration ("FDA") submits this memorandum in support of its Motion for an Eighteen-Month Stay of Proceedings. FDA moves for a stay because "exceptional circumstances exist" and it "is exercising due diligence in responding to the [FOIA] request." 5 U.S.C. § 552(a)(6)(C). Alternatively, the Court may grant this 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). Plaintiff, through counsel, intends to oppose this motion. *See infra* at n.2.

Exceptional circumstances exist because of two concurrent orders entered in two Freedom of Information Act ("FOIA") cases pending in the Northern District of Texas. Under those out-of-circuit orders, FDA's Access Litigation and Freedom of Information Branch (the "Branch"), which is within FDA's Center for Biologics Evaluation and Research (the "Center") and is responsible for reviewing and releasing records maintained by the Center, is facing an unprecedented workload requiring FOIA productions involving approximately 5.7 million pages of COVID-19 vaccine records in a compressed timeframe. *See Pub. Health & Med. Pros. for Transparency* ("*PHMPT*") *v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT 1*") and *PHMPT v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT 2*"); *see also* Ex. 1 hereto (Declaration of Suzann Burk ("Burk Decl.")) ¶ 7. Collectively, *PHMPT 1* and *PHMPT 2* require the Center to produce at least 90,000 to 110,000 pages per month from July 2023 through November 2023, and, starting in December, at least 180,000 pages per month until June 2025.[1] *Id.* These unprecedented productions have been ordered

[1] A copy of the *PHMPT 2* order, which provides a table summarizing the Branch's *PHMPT 1* and *PHMPT 2* minimum monthly productions over the coming months, is attached to the Burk Declaration, which is enclosed herewith as Exhibit 1.

alongside a backdrop of other increased workload obligations, including a tremendous increase in incoming FOIA requests and FOIA litigation stemming, in large part, from requests related to the Center's work pertaining to the COVID-19 pandemic. *Id*.

The Agency is exercising due diligence. FDA has made and continues to make extraordinary efforts to hire, train, and maximize efficiencies to comply with these court orders and its other FOIA obligations. Among other things, the Branch hired and trained contractors (approximately nine full-time and one part-time) to focus on processing records in *PHMPT 1*, at an estimated cost of approximately $3.5 million through October 2023. *Id*. ¶ 25. Recently, six new full-time employees have joined the Branch (at an estimated annual cost of $1.8 million) and are currently being onboarded and trained. *Id*. However, it takes approximately two years for new employees to be fully trained. *Id*. ¶ 30. The training process initially slows the pace of processing outstanding requests because more senior employees must review the new employees' work, line-by-line, to ensure that records are being correctly reviewed for necessary redactions. *Id*. Thus, despite the Branch's good-faith investment in increasing its future processing capacity by training new employees, its resources remain limited during this lengthy onboarding period. *Id*.

In addition to the power to grant an *Open America* stay under 5 U.S.C. § 552(a)(6)(C), this Court also has inherent authority to grant a stay under *Landis v. North American Co.*, 299 U.S. 248 (1936). To issue a *Landis* stay, a court weighs the specific hardships to the parties and the interest in judicial economy. *See id.* at 255. Here, FDA can show specific and unprecedented hardships from *PHMPT 1* and *PHMPT 2*, and a limited stay of this action will not harm Plaintiff, particularly given the abundance of COVID-19 vaccine-related information already made publicly available by FDA.

Accordingly, this Court should grant FDA an eighteen-month stay, at the end of which FDA will file a status report advising the Court of its circumstances and whether it needs additional time before proceeding with this case. This stay will help the Branch triage its limited resources to respond to the broad range of requests it continues to receive, while complying with existing court orders and helping FDA to ensure that, when it does turn to the instant request, it can conduct an appropriate review of collected records to determine responsiveness, followed by a careful review of responsive records to determine releasability.[2]

BACKGROUND

This action stems from two FOIA requests submitted by Plaintiff Children's Health Defense ("CHD") seeking records concerning data analyses conducted by FDA or the Centers for Disease Control and Prevention ("CDC") in accordance with CDC's *Vaccine Adverse Event Reporting System Standard Operating Procedures for COVID-19* to evaluate whether adverse events (possible side effects) are being reported more frequently after the administration of a COVID-19 vaccine than after the administration of other vaccines. The adverse event reports are contained in the Vaccine Adverse Event Reporting System, which is a national vaccine safety surveillance database maintained by FDA and CDC. Reports of such adverse events may be submitted to this database by any concerned individual, including health care providers, vaccine manufacturers, vaccine recipients (or their parents or guardians), and state immunization programs.[3] The reports themselves generally cannot be used to determine the cause of an adverse event; they are reviewed "for any unexpected patterns or changes in rates of adverse events." FDA,

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[2] Government counsel and Plaintiff's counsel conferred about this motion on August 11, 2023. Plaintiff informed the government that it anticipates it will oppose this motion. *See* Joint Status Report (Aug. 11, 2023), ECF No. 15, ¶ 10; LCvR 7(m).

[3] The public can access data in this database at https://wonder.cdc.gov/vaers.html.

VAERS Overview, https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview (last accessed Aug. 29, 2023).

In its lawsuit, CHD seeks records of data analyses conducted pursuant to the *Vaccine Adverse Event Reporting System Standard Operating Procedures for COVID-19* (January 29, 2021 version) as follows:

> Records of any Empirical Bayesian data mining conducted by FDA . . . , and records of any sharing or discussion of results and signals with the CDC;
>
> Records of any results and signals received by FDA . . . from the CDC's own Proportional Reporting Ratio data mining, and any discussion of those results;
>
> Records of any manual review of serious AESI [Adverse Events of Special Interest] reports conducted by FDA . . . ; and
>
> Records of any consultations by FDA . . . with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected.

See ECF No. 1-1 at 5. CHD's lawsuit also seeks "records of the Empirical Bayesian data mining described on pages 9-10 of the article, '*Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021.*'" *See* ECF No. 1-1 at 40.

To date, FDA has completed its search for records "of any results and signals received by FDA . . . from the CDC's own Proportional Reporting Ratio data mining, and any discussion of those results" and determined that the records it collected are not responsive to this request. *See* Joint Status Report (Aug. 11, 2023), ECF No. 15, ¶ 6. FDA also collected approximately 150 records while searching for records containing or relating to "Empirical Bayesian data mining conducted by FDA. . . , and records of any sharing or discussion of results and signals with the CDC" and determined that these records are responsive to CHD's request. *Id.* ¶ 7. Finally, FDA completed its search for "records of the Empirical Bayesian data mining described on pages 9-10 of the article, '*Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination,*

December 14, 2020-November 17, 2021" and produced the responsive record to CHD. *See* Joint Status Report (June 27, 2023), ECF No. 14, ¶ 4; *see also* Joint Status Report (Aug. 11, 2023), ECF No. 15, ¶ 6.

FDA still has to complete additional searches for records "of any Empirical Bayesian data mining conducted by FDA . . . , and records of any sharing or discussion of results and signals with the CDC" and conduct searches for records "of any manual review of serious [Adverse Events of Special Interest] reports conducted by FDA" and "of any consultations by FDA . . . with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected." Jt. Status Rep. (Aug. 11, 2023), ECF No. 15, ¶ 8. Upon completing these searches, FDA must review the 150 records mentioned above and the records it collects from these remaining searches to determine whether these records are responsive and whether any information in responsive records is exempt from disclosure.

LEGAL STANDARDS

To obtain a stay in a FOIA case, the government may satisfy the requirements of either 5 U.S.C. § 552(a)(6)(C)(i) or *Landis*.

I. 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).

Section 552(a)(6)(C) was given its definitive interpretation in *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976). There, 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 Court 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 when there is, for example, a substantial, unpredictable increase in the number of FOIA requests that an agency receives. *See Elec. Frontier Found.*, 517 F. Supp. 2d 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. 12-0313, 2014 WL 12912625, at *2 (D.D.C. Dec. 8, 2014) (finding "exceptional circumstances" where a repeat plaintiff filed 81 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 have reasonably planned for a single citizen to consume such a vast quantity of the agency's FOIA resources").

Exceptional circumstances also can be shown by an increase in FOIA litigation. For example, this Court found exceptional circumstances existed 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. S.E.C.*, 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, 162 (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"); *see also 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 "OMB has exercised due diligence by processing Plaintiffs' FOIA request within OMB's 'multi-track' processing system," under which "OMB resolves 'simple' and 'expedited' requests in an expedited fashion, while OMB 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).

A stay, moreover, will help ensure that the Agency, when in a position to resume processing the requests here at issue, will have the resources available to safeguard the "important interests" protected by FOIA's exemptions to protect, among other things, the personal medical and other information of absent third parties. *See Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) (cleaned up).

II. Inherent Authority to Stay Proceedings under *Landis*

An alternative ground for issuance of a 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 proceedings. *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 to allow Office of Legal Counsel to evaluate the agency's position regarding refined claims in an amended complaint); *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 JSW, 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).

ARGUMENT

I. The Court Should Grant an Eighteen-Month Stay Under 5 U.S.C. § 552(a)(6)(C)(i) Because FDA Can Demonstrate "Exceptional Circumstances" and "Due Diligence."

This Court should grant FDA's requested stay under Section 552(a)(6)(C)(i) because FDA can show: (1) "exceptional circumstances" based on the unprecedented court orders requiring voluminous productions in *PHMPT 1* and *PHMPT 2* and significant increases in FOIA requests and litigation involving the Branch; and (2) "due diligence" based on the extraordinary 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.

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

The Branch is facing "exceptional circumstances." The concurrent court-ordered productions in *PHMPT 1* and *PHMPT 2* involve approximately 5.7 million pages of COVID-19 vaccine-related records and collectively require the Branch to produce records at rates totaling 90,000 to 180,000 pages per month beginning in July 2023. At the same time, the Branch faces an increased number of FOIA requests and lawsuits. The number of requests has approximately tripled in the past ten years, further straining the agency's limited resources and ability to perform the requisite, careful, line-by-line review of all records before production that is necessary to protect confidential commercial and personal privacy information as required by law. *See* Burk Decl. ¶ 18-19.

Prior to the 2022 production order in *PHMPT 1*, the Branch was able to keep its FOIA queues relatively low and stable with nine regular staff and one branch chief. Burk Decl. ¶ 18. From fiscal years 2015 to 2018, the number of FOIA requests received by the Center 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*. The number and complexity of FOIA requests began to increase in FY 2019. *Id.* ¶ 19. By FY 2021, the Center began to receive more than 500 requests annually, with 509 requests in FY 2021 and 633 requests in FY 2022. *Id*. By the end of FY 2022, the number of pending FOIA requests grew to 532. *Id*. Moreover, in FY 2020, FOIA suits added significantly to the Branch's workload. *Id*. Prior to FY 2020, few suits involving the Branch were filed; today, it is involved in twelve cases,[4] including this one. *Id*. ¶¶ 18-19, 21. The Burk Declaration provides two tables summarizing these trends. *Id*. ¶¶ 18-19. Although FY 2023 data is not yet complete, the data collected as of June 30, 2023, shows that the number of pending FOIA requests—660—has continued to grow under the strain of increased FOIA litigation and increased requests. *Id*. ¶ 21.

In *PHMPT 1*, the United States District Court for the Northern District of Texas ordered FDA to produce records beginning in March 2022 at an unprecedented average rate of 55,000 pages per month. Burk Decl. ¶ 23. The *PHMPT 1* records comprise over 1.1 million pages related

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[4] In addition to *PHMPT 1* and *PHMPT 2*, the Branch is involved in the following cases (with the dates on which their Complaints were originally filed): *Wright v. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-1378 (RC) (D.D.C.) (May 18, 2022); *Defending the Republic v. FDA*, Civ. A. No. 22-1237 (N.D. Tex.) (June 7, 2022); *de Garay v. FDA*, Civ. A. No. 22-0512 (S.D. Ohio) (Sept. 3, 2022) (plaintiffs in *de Garay* are also plaintiffs in *PHMPT 2*); *Informed Consent Action Network* ("*ICAN*") *v. FDA*, Civ. A. No. 22-3572 (CKK) (D.D.C.) (Nov. 23, 2022); *ICAN v. FDA*, Civ. A. No. 23-0219 (RBW) (D.D.C.) (Jan. 25, 2023); *Children's Health Def.* ("*CHD*") *v. FDA*, Civ. A. No. 23-0220 (RDM) (D.D.C.) (Jan. 26, 2023); *ICAN v. FDA*, Civ. A. No. 23-1508 (CKK) (D.D.C.) (May 25, 2023); *Protect the Pub.'s Tr. v. FDA*, Civ. A. No. 23-2322 (DLF) (D.D.C.) (Aug. 10, 2023); *CHD v. FDA*, Civ. A. No. 23-2316 (TJK) (D.D.C.) (Aug. 10, 2023); and *ICAN v. FDA*, Civ. A. No. 23-1088 (W.D. Tex.) (Sept. 11, 2023). FDA is also moving for eighteen-month stays in two of these FOIA cases: *ICAN v. FDA*, Civ. A. No. 23-0219 (RBW) (D.D.C.), and *ICAN v. FDA*, Civ. A. No. 23-1508 (CKK) (D.D.C.).

to Pfizer-BioNTech's Comirnaty vaccine for COVID-19 approved for individuals 16 years of age and older. *Id*. FDA anticipates that production of *PHMPT 1* records will be completed by November 2023. *Id*. Given that the production rate ordered in *PHMPT 1* far exceeded FOIA production rates typically ordered by courts, the Center's Division of Disclosure and Oversight Management, and the Branch, which it oversees, 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*. ¶ 24.

While the Branch's extraordinary efforts to marshal resources to comply with the *PHMPT 1* order were ongoing, PHMPT and other parties represented by the same attorneys sued FDA again in *PHMPT 2*. *Id*. ¶ 26. In *PHMPT 2*, the records at issue are estimated to be over 4.5 million pages relating both to FDA's approval of Pfizer's Comirnaty vaccine for 12 to 15-year-olds and Moderna's Spikevax vaccine. *Id*.

The same court imposed an even more intense monthly production schedule on the Center. *PHMPT 2*, ECF No. 38. From July 2023 to November 2023, the Branch is required to produce 90,000 to 110,000 pages per month in *PHMPT 1* and *PHMPT 2* collectively. *Id*. Then, beginning in December 2023, after the *PHMPT 1* production has concluded, the Branch must produce 180,000 pages per month in *PHMPT 2*. *Id*. And production of all responsive records must be completed by June 30, 2025. *Id*. To FDA's knowledge, this production rate is many orders of magnitude greater than anything any agency has ever encountered in a FOIA production order. Burk Decl. ¶ 26. These unprecedented 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 for 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).

B. FDA is Exercising "Due Diligence."

As described in the Burk Declaration, the Branch 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. *Id.* ¶ 12. This alone is sufficient to show "due diligence." *See 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 *PHMPT 1* and *PHMPT 2* orders and fulfill its other responsibilities stemming from increased FOIA requests and litigation, the Center's FOIA office has undertaken immediate and aggressive efforts to hire additional staff and contractors, seek funding, and reorganize its resources. Burk Decl. ¶¶ 24-26, 28-29. As noted above, prior to *PHMPT 1*, the Branch consisted of nine regular staff supervised by one branch chief. Burk Decl. ¶ 18. After the *PHMPT 1* order, the Branch made large-scale changes to its staff and work processes. Among other things, the Branch hired contractors (nine full-time and one part-time) to focus on processing records for the *PHMPT 1* litigation. *Id.* ¶ 24. The cost of contractors for processing records in *PHMPT 1* will total approximately $3.5 million through October 2023. *Id.* ¶ 25. This past spring, the Branch received approval to hire six full-time employees, which will cost an estimated additional $1.8 million annually (in salary, benefits, taxes, and other employee-related expenses). *Id.* After the *PHMPT 1* order issued, the Branch was able eventually to assign nine full-time

employees to focus primarily on the *PHMPT 1* production, leaving a smaller team of six full-time employees to assume primary responsibility for all other FOIA requests. *Id*. ¶ 24.

Now, with *PHMPT 2* straining the nine full-time employees and 9.5 contractors assigned primarily to *PHMPT 1*, the Branch is working aggressively to meet concurrent production orders totaling 90,000 to 110,000 pages per month in the immediate coming months, a burden that will ramp up to 180,000 pages per month in December 2023. Since the *PHMPT 2* order issued, the Center has triaged resources to meet the July and August deadlines in *PHMPT 1* and *PHMPT 2*, once again reorganizing staffing and leaving only a handful of staff working on all non-litigation FOIA requests. *Id*. ¶ 28. Additionally, the Center's Division of Disclosure and Oversight Management is reassigning staff as available to assist in the review of the Branch-managed records. *Id*.

While it is ramping up production, the Branch is also diligently working to hire additional staff and contractors who will be critical to ensuring that FDA can comply with the existing Texas production orders going forward—efforts that will require the Branch to seek substantial monetary resources during a time of budgetary uncertainty. *Id*. ¶ 29. Determining the number of employees/contractors needed for these enormous productions while factoring in the availability of necessary financial resources requires on-going, complex discussions with entities within and outside the Center. *Id*.

Importantly, while the Center's ongoing hiring and training efforts demonstrate the agency's "due diligence" and good-faith investment to comply with its court-ordered production mandates and address the existing backlog of FOIA requests (including those submitted by Plaintiff in this case), its efforts are limited by the lengthy ramp-up period for hiring and training new employees. *Id*. ¶ 30. Thus, even if the Center is awarded the resources it hopes to add to the

Branch, receiving funds and hiring are merely the first steps in a labor-intensive process needed to onboard employees so that they can contribute to the Branch's disclosure efforts. *Id*. The process of advertising, recruiting, interviewing, and conducting administrative onboarding alone takes several months (assuming a qualified candidate is found). *Id*. While new employees are in training, current staff must spend time partnering with them to provide training and oversight. *Id*. Staff must review new employees' work to ensure that personal privacy, trade secrets, and other protected information is not inadvertently disclosed. *Id*. All told, after a new employee is onboarded, it takes approximately two years for an employee to be fully trained so that he or she can meaningfully contribute to the Branch's disclosure efforts. *Id*.

Thus, the extraordinary efforts the Branch has undertaken in significantly expanding its numbers of staff/contractors, 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.

II. The Court Should Exercise Its Inherent Authority to Stay This Action Under ***Landis.***

This Court may also exercise its inherent, equitable authority to grant a stay under *Landis*. "A federal district court 'has broad discretion to stay proceedings as an incident to its power to control its own docket.'" *Ctr. for Biological Diversity v. Ross*, 419 F. Supp. 3d 16, 20 (D.D.C. 2019) (quoting *Clinton v. Jones*, 520 U.S. 681, 706 (1997), which in turn cites *Landis*, 299 U.S. at 254). 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). Thus, courts consider: (1) the injury to the movant if the litigation proceeds without a stay, (2) the injury to the non-movant in granting a stay, and (3) the court's

interest in judicial economy. *See Hulley Enters. Ltd. v. Russian Fed'n*, 502 F. Supp. 3d 144, 152 (D.D.C. 2020). All three factors militate in favor of granting a stay here.

First, FDA will suffer serious hardship if this case is allowed to go forward at this time. As described in the preceding sections, the Branch already is triaging its limited resources and working at full capacity to address an extraordinary workload brought on by *PHMPT 1* and *PHMPT 2* and other essential obligations. Without any relief in the next eighteen months, the Branch may not be able to conduct a line-by-line review of all records to protect confidential information and may be at risk of violating court orders, which would subject the agency to the threat of sanctions.

Second, Plaintiff will not be injured by an eighteen-month stay, as it has not articulated a specific need for these documents or a specific urgency. Moreover, the amount of information already available with respect to COVID-19 vaccines (including the hundreds of thousands of Comirnaty vaccine records already produced in *PHMPT 1*) mitigates any potential "injury" Plaintiff might suffer. Indeed, to inform the public about its work related to the COVID-19 vaccines, FDA has published on its website the most important safety and efficacy information about Moderna's Spikevax vaccine, Pfizer-BioNTech's Comirnaty vaccine, and the supplemental approval of the Comirnaty vaccine for use in individuals ages 12 to 15 years old. Among other things, a Moderna-specific webpage provides updated information about the Spikevax vaccine and Moderna's bivalent booster vaccine. *See* FDA, *Moderna's COVID-19 Vaccines*, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines (last updated June 6, 2023).[5] Similarly, a Pfizer-specific webpage provides focused

[5] This webpage includes links to other webpages, including a link to the "Action Package" for Spikevax, which includes the Clinical Review Memorandum (which in turn provides

and updated information about the Comirnaty vaccine and its bivalent booster vaccine. *See* FDA, *Pfizer-BioNTech COVID-19 Vaccines*, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines (last updated July 14, 2023).[6]

Third, a stay will promote judicial economy by simplifying issues before this Court. Currently, because of the Branch's other commitments, the Branch is not able to agree to a processing schedule. After an eighteen-month stay, the Branch will be better situated to update the Court on its ability to process any responsive records in this case.

In sum, all three *Landis* factors weigh in favor of an eighteen-month stay of this case.

* * *

information about individual clinical trials, safety and efficacy, and risk-benefit considerations and recommendations, among other things), Package Inserts, Approval Letter, and the Summary Basis for Regulatory Action.

[6] This webpage includes links to other webpages, including a link to the "Action Package" for Comirnaty, which includes the Clinical Review Memorandum (which in turn provides information about clinical trial safety and efficacy, and risk-benefit considerations and recommendations, among other things), the Statistical Review, Package Inserts, Approval Letters, and the Summary Basis for Regulatory Action.

CONCLUSION

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

Date: September 14, 2023
Washington D.C.

Respectfully submitted,

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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)

[PROPOSED] ORDER

UPON CONSIDERATION of Defendant's motion for a stay, and the entire record herein, it is hereby:

ORDERED that Defendant's motion is GRANTED;

ORDERED that this action is STAYED for eighteen months from the date of entry of this order; and it is further

ORDERED that Defendant will file a status report at the end of the eighteen-month stay outlining its proposal for further proceedings in this case, and that beginning six months from the date of entry of this order, Defendant shall update the Court every six months with its most recent status reports regarding its progress in complying with *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) and *Public Health & Medical Professionals for Transparency v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.).

SO ORDERED:

Date

RANDOLPH D. MOSS
United States District Judge