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

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

**PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO ALTER OR AMEND JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 59(e)**

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Cases**



**Statutes**



**Other Authorities**

Public Health and Medical Professionals for Transparency ("**PHMPT**" or "**Plaintiff**") respectfully submits this Opposition to the Food and Drug Administration's ("**FDA**") Motion to Alter or Amend Judgment Pursuant to Federal Rule of Civil Procedure 59(e).

## INTRODUCTION

This case presents the classic scenario of "[t]he man who murdered his parents, and then pleaded for mercy on the grounds that he was an orphan."[1] Here, the man pleading for mercy is FDA, which has once again self-inflicted the harm about which it now complains while attributing it to Plaintiff—namely, stonewalling and refusing to produce the "data and information in the biological product file" for Pfizer's COVID-19 vaccine that was supposed to be "immediately available for public disclosure" nearly three and a half years ago. 21 C.F.R. § 601.51(e). FDA must not be rewarded for this ongoing unscrupulous behavior.

For three separate reasons, FDA's instant motion should be denied. First, FDA could have, yet failed to, raise all of the arguments in its Motion to Alter or Amend Judgement Pursuant to Federal Rule of Civil Procedure 59(e) in response to Plaintiff's Cross-Motion for Summary Judgment. This alone is dispositive of the motion, which should be denied. Second, FDA is not entitled to a stay for exceptional circumstances pursuant to the Freedom of Information Act ("**FOIA**") as it has not shown due diligence in its handling of this request. Quite the contrary—the parties are here before this Court due solely to FDA's illegal and unjustified withholding of responsive records. Third, at least two of the three *Landis* factors weigh against any stay: the damage that will result to Plaintiff and all Americans from the granting of a stay, and judicial economy.

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[1] https://www.goodreads.com/quotes/359784-hypocrite-the-man-who-murdered-his-parents-and-then-pleaded.

Because the Court is exceedingly familiar with the facts and history of this case, and in the interest of judicial economy, Plaintiff restricts its brief to only the following limited salient points.

## LEGAL STANDARD

### I. FEDERAL RULE OF CIVIL PROCEDURE 59(E) – MOTION TO ALTER OR AMEND A JUDGMENT

Federal Rule of Civil Procedure 59(e) serves "the narrow purpose of allowing a party to correct manifest errors of law or fact or to present newly discovered evidence." *Templet v. Hydrochem, Inc.*, 367 F. 3d 473, 479 (5th Cir. 2004). District courts have "considerable discretion in deciding whether to reopen a case under Rule 59(e)." *Edward H. Bohlin Co. v. The Banning Co.*, 6 F.3d 350, 355 (5th Cir. 1993). "A Rule 59(e) motion to alter a judgment is an extraordinary remedy that should be granted sparingly." *Matthews v. Tidewater*, 108 F.4th 361, 371 (5th Cir. 2024) (internal citations omitted).

A Rule 59(e) motion "may not be used to relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 485 n.5 (2008) (quoting 11 C. Wright & A. Miller, Federal Practice and Procedure § 2810.1, at 127-28 (2d ed. 1995); *see also Templet*, 367 F.3d at 479 ("[A Rule 59(e)] motion is not the proper vehicle for rehashing evidence, legal theories, or arguments that could have been offered or raised before the entry of judgment.").

### II. 5 U.S.C. § 522(A)(6)(C)(I)

"Congress's insistence that agencies timely respond to FOIA requests is . . . apparent from the face of the statute." *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 58 (D.D.C. 2018). Specifically, FOIA provides that, upon receipt of a request, a responding agency must "determine within 20 days . . . whether to comply with such request and shall immediately notify [the requestor]." *Id.* (quoting 5 U.S.C. § 552 (a)(6)(A)(i)). The statute only allows an agency

to grant itself an additional 10 days to respond in "unusual circumstances" so long as the agency notifies the requestor of the unusual circumstances and specifies "the date on which a determination is expected to be dispatched." *Id.* Then, "[u]pon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request." *Id.* (quoting 5 U.S.C. § 552(a)(6)(C)(i)). Thus, it is apparent that Congress carefully crafted FOIA to put a substantial burden on the government to justify any noncompliance within the time limit prescribed under FOIA – generally speaking, no more than 30 business days. To be sure, "Excessive delay by the agency in its response is often tantamount to denial. It is the intent of this bill that the affected agencies be required to respond to inquiries and administrative appeals within specific time limits." *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 617 (D.C. Cir. 1976) (Levanthal, J., concurring) (quoting H. Rep. No. 93-876, 93d Cong., 2d Sess. (1974), U.S. Code Cong. & Ad. News, p. 6271).

While Congress provided agencies with a limited "safety valve" from the strict time limits afforded by the statute (*id*. at 610), it nevertheless requires agencies to show that "exceptional circumstances exist, **and that the agency is exercising due diligence in responding to the [FOIA] request**" to obtain a stay. *Democracy Forward Found.*, 354 F. Supp. 3d at 58 (quoting 5 U.S.C. § 552 (a)(6)(C)(i)) (emphasis added). In this Circuit, such stays are commonly referred to as "*Open America* stays," so named after the leading decision on the subject. *Id.* In *Open America*, the D.C. Circuit held:

> [W]e interpret Section 552(a)(6)(C) to mean that "exceptional circumstances exist" when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it "is exercising due diligence" in processing the requests.

547 F.2d at 616 (quoting 5 U.S.C. § 552 (a)(6)(C)).

In 1996 Congress amended FOIA to narrow the definition of "exceptional circumstances." 5 U.S.C. § 552(a)(6)(C)(ii) provides:

> For purposes of this subparagraph, the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

*Democracy Forward Found.*, 354 F. Supp. 3d at 59 (quoting 5 U.S.C. § 552 (a)(6)(C)(ii)).

Hence, the safety valve provisions of 5 U.S.C. § 552(a)(6)(C) were carefully crafted to put a substantial burden on the government to justify to the courts any noncompliance with FOIA time limits. *Open America*, 547 F.2d 605 at 617 (Levanthal, concurring).

## III. INHERENT AUTHORITY TO STAY PROCEEDINGS UNDER *LANDIS*

It is true that the authority 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. However, stays are nevertheless "an 'intrusion into the ordinary processes of administration and judicial review,'" *Huddleston v. FBI*, Civ. A. No. 20-0447, 2021 WL 1837548, at *2 (E.D. Tex. May 7, 2021) (citing *Nken v. Holder*, 556 U.S. 418, 427, 129 S. Ct. 1749, 173 L. Ed. 2d 550 (2009) (quoting *Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925, 104 U.S. App. D.C. 106 (D.C. Cir. 1958) (per curiam)), and they are "not a matter of right, **even if irreparable injury might otherwise result**." *Id*. (citing *Virginian R. Co. v. United States*, 272 U.S. 658, 672 (1926)) (emphasis added). Instead, stays are "an exercise of judicial discretion, and the 'party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.'" *Id*. (citing *Ind. State Police Pension Tr. v. Chrysler LLC*, 556 U.S. 960, 961 (2009) (per curiam) (quoting *Nken*, 556 U.S. at 433-

34); *see Exner v. FBI*, 542 F.2d 1121, 1123 (9th Cir. 1976) (explaining that the responding agency bears the burden to demonstrate its due diligence in fulfilling its FOIA-related obligations). Indeed, a court's stay order "must be supported by 'a balanced finding that such need overrides the injury to the party being stayed.'" *Belize Soc. Dev. Ltd. v. Govt. of Belize,* 668 F.3d 724, 732 (D.C. Cir. 2012) (quoting *Dellinger v. Mitchell*, 442 F.2d 782, 787 (D.C. Cir. 1971)). "[I]f there is even a fair possibility that the stay . . . will work damage to someone else," the movant "must make out a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255.

In deciding whether to exercise that power, courts must "weigh competing interests and maintain an even balance between the court's interest in judicial economy and any possible hardship to the parties." *Belize Soc. Dev. Ltd.,* 668 F.3d at 732-33 (quoting *Landis,* 299 U.S. at 254); *Wolf Designs, Inc. v. Donald McEvoy Ltd., Inc.*, 355 F. Supp. 2d 848, 853 (N.D. Tex. 2005) (citing *Landis*, 299 U.S. at 254-55); *CMAX, Inc. v. Hall*, 300 F.2d 265, 268 (9th Cir. 1962) (Holding that it is the district court's responsibility to weigh the competing interests of the parties relating to the appropriateness of a stay). Identifying and weighing these "competing interests" of "possible hardship[s]," and "judicial economy," (*id.*) requires the court to "make such determinations in the light of the particular circumstances of the case." *SEC v. Dresser Indus., Inc.*, 628 F.2d 1368, 1375 (D.C. Cir. 1980). Specifically, the Court must examine: (1) the possible damage that may result from the granting of a stay, (2) the hardship or inequity that a party may suffer in being required to go forward, and (3) the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay. *See CMAX,* 300 F.2d at 268; *Landis*, 299 U.S. at 254-55.

In *Landis*, the Supreme Court instructed that a court abuses its discretion in ordering a stay "of indefinite duration in the absence of a pressing need." *Landis*, 299 U.S. at 255. A stay is

"immoderate and hence unlawful unless so framed in its inception that its force will be spent within reasonable limits, so far at least as they are susceptible of prevision and description," and "an order which is to continue by its terms for an immoderate stretch of time is not to be upheld as moderate because conceivably the court that made it may be persuaded at a later time to undo what it has done." *Id*. at 257. Underlying the Court's analysis was a recognition that "[o]nly in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both." *Id*. at 255.

## ARGUMENT

### I. THE COURT SHOULD NOT ALTER OR AMEND ITS DECEMBER 6, 2024 ORDER

#### A. FDA Has Not Demonstrated a Manifest Error of Law or Fact and Therefore Is Not Entitled to an Amendment or Alteration Pursuant to FRCP 59(e)

Plaintiff moved for summary judgment, which was granted by the Court, and in so doing, sought production to be completed by February 20, 2025. (Dkts. 93 and 94.) Defendant had the opportunity to oppose that motion, which it did. (Dkts. 97-99.) In its opposition, Defendant could have litigated the issue of the production schedule and argued about the burden it would face in having to produce the records by Plaintiff's requested date. It did not. It may not now use a Rule 59(e) motion to "relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment." *Exxon Shipping Co.*, 554 U.S. at 485 n.5 (quoting 11 C. Wright & A. Miller, Federal Practice and Procedure § 2810.1, at 127-28 (2d ed. 1995)). Nothing prevented FDA from raising any of the arguments in its current motion in its opposition to Plaintiff's motion for summary judgment, before the entry of the Court's judgment. Its instant Rule 59(e) motion "is not the proper vehicle for rehashing evidence, legal theories, or arguments that could have been offered or raised before the entry of judgment." For this reason alone, the Court may summarily deny Defendant's motion.

**B. FDA Cannot Demonstrate Either "Exceptional Circumstances" Or "Due Diligence" and Therefore Is Not Entitled to an Amendment or Alteration Pursuant to 5 U.S.C. § 552(a)(6)(C)(i)**

As it has numerous times throughout both the PHMPT cases, as well as others, FDA insists that it is facing "exceptional circumstances"—this time because it must comply with the Court's orders in *PHMPT II*[2]and, now, the Court's December 6, 2024 Order which, according to FDA, adds at least 589,600 pages to its production. This is simply not the case.

As explained in *Open America*, under Section 552(a)(6)(C),

> "exceptional circumstances exist" when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it "is exercising due diligence" in processing the requests.

547 F.2d at 616 (quoting 5 U.S.C. § 552 (a)(6)(C)).

There are at least two reasons why exceptional circumstances do not exist here. First, FDA unquestionably knew or should have known, in 2020, when the pandemic began, that there would be a predictable increase in FOIA requests. As early as January 2020, FDA was taking actions that suggested it knew the pandemic was going to be a massive public health issue inviting tremendous public scrutiny, which invariably means FOIA requests.[3] Had FDA acted on this knowledge at the time and prepared, it would have had over four years to train new staff. Indeed, it did not take

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[2] *PHMPT II* refers to *Public Health and Medical Professional for Transparency et al. v. FDA*, No, 4-22-cv-00915-P.

[3] For example, on January 27, 2020, FDA issued a press release listing a number of actions it was planning to take. *See* https://www.fda.gov/news-events/press-announcements/fda-announces-key-actions-advance-development-novel-coronavirus-medical-countermeasures. Significantly, even at that early date, the press release provided an email for "[s]ponsors wishing to develop therapeutics for 2019-nCoV [who were] are encouraged to submit information and questions," suggesting FDA was well aware of, and was encouraging, the development and rapid submission of applications for medical products to combat the outbreak. *Id.*

action at the start of the pandemic, nor did it take action in response to Plaintiff's original FOIA request on August 27, 2021, nor in response to the suit that followed on September 16, 2021; only when finally forced to as a result of this Court's January 6, 2022 order did FDA take action to increase its FOIA output. By no measure can FDA show it has been exercising due diligence or taking *proactive* steps to uphold its statutory responsibilities prior to court intervention. For this reason alone, the Court should find that exceptional circumstances do not exist to alter the December 6, 2024 order.

But there is yet another reason that exceptional circumstances do not exist. Aside from FDA's failure to act with due diligence in carrying out its FOIA obligations overall, it has, more specifically, failed to act with due diligence in carrying out its obligations pursuant to the instant request and the Court orders in this suit. FDA's argument that it has made general staffing and resource improvements cannot substitute for evidence that it acted diligently and in good faith to process this request in the first place. Had the FDA exercised due diligence, the EUA file would have been produced earlier, avoiding the need for judicial intervention. As such, the agency cannot meet the burden required to justify a stay or any alteration of the Court's production schedule.

More specifically, as the Court ruled in its December 6, 2024 Memorandum Opinion and Order, legally, the "additional" documents that FDA presently claims are too burdensome to produce are not, in fact, additional. These documents, the Court held, should have been produced based in response to the original request: "the EUA is disclosable data as requested by Plaintiff and defined in 21 C.F.R. § 601.51." *Public Health Profs. for Transp. v. FDA*, 4:21-cv-01058, at 6 (N.D. Tex. Dec. 6, 2024) [hereinafter *PHMPT I*]. FDA steadfastly chose not to produce these documents, despite *repeated* requests by, and discussions with, Plaintiff. Ultimately, Plaintiff was forced to expend additional time, energy, and legal fees to seek relief, yet again, from the Court.

Unsurprisingly, the Court found what FDA knew all along—the documents FDA relied upon to approve the Pfizer COVID-19 vaccine, including the EUA file, did have to be produced in response to Plaintiff's FOIA request.

The crucial point is that these documents should have been produced in the first place and FDA knew or, at the very least, should have known it. The fact that they were not produced, compounded with the fact that FDA fought tooth and nail when it was pointed out, means FDA has inherently not acted with due diligence in responding to Plaintiff's FOIA request. FDA created its current predicament by illegally and unjustifiably withholding responsive documents that were owed to Plaintiff (and the American public). Now that there is a Court order solidifying this fact, FDA seeks relief from the Court for its own self-inflicted wound. It would be wholly inappropriate to reward this behavior with yet more time in the form of a stay. It is solely the fault of FDA that the documents in the EUA file have not yet been searched for, counted, processed, and produced. Therefore, it should be solely FDA, and not Plaintiff nor the American public, that suffer the consequences of this behavior.

In seeking a stay here, FDA circularly notes that it has obtained approximately thirteen stays in other cases by pointing to its obligations in this case and in *PHMPT II*. Now, FDA is attempting to point to those thirteen stays in order to try to obtain a stay in this case. In essence, FDA has told the court in the District of Columbia in multiple cases that it cannot produce FOIA documents because of the *PHMPT I* and *II* cases. Having obtained those stays, FDA then comes back to this Court, saying, "FDA got a stay in its District of Columbia cases and so it is entitled to a stay, here, too." This is the classic circular reasoning of FDA: "heads I win, tails you lose." Notably, the stays it has obtained in those 13 cases have freed the agency up to focus on producing the records at issue in the *PHMPT I* and *II* cases; it should have allowed FDA to "conduct a careful

review" as it claims is important (Dkt. 104 at 6), yet here we are. Despite having obtained stays elsewhere and having been able to focus on this case, FDA still did not conduct a careful review and has instead created the very bed it now complains of having to lie in. At no point has FDA ever expressed any comprehension or recognition of the American public's need for these COVID-19 vaccine documents – the very public who paid for these vaccines and then, in many cases, was mandated to take them. Instead, as is once again on display here, FDA almost universally and reflexively opposes all transparency and treats those who ask for it with hostility. Plaintiff urges the Court not to further FDA's misconduct or reward it by granting its instant Motion.

## II. *LANDIS* DOES NOT SUPPORT ALTERING OR AMENDING THE DECEMBER 6, 2024 ORDER WITH A STAY

While FDA recites, in elaborate detail, all of the "extraordinary" steps it waited to implement until forced to do so by the Court's January 6, 2022 order, as well as the purported hardship it will endure if forced to comply,[4] none of that can change that at least two, if not all three, of the *Landis* factors weigh strongly against a stay.

Under *Landis*, the court considers: (1) the possible damage that may result from the granting of a stay, (2) the hardship or inequity that a party may suffer in being required to go forward, and (3) the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay. *See CMAX,* 300 F.2d at 268; *Landis*, 299 U.S. at 254-55.

With respect to the first factor, if the Court determines that there is even a fair possibility the stay will damage Plaintiff's interest, FDA's burden becomes even heavier, for it must then show

[4] It is worthwhile to note, once again, that the information sought in this request was, by law, supposed to be made "**immediately available for public disclosure**." 21 C.F.R. § 601.51(e). It is hard to argue that "immediately" means more than 4 years later.

"a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255. Unquestionably, here, both Plaintiff's (and the American public's) interest will be injured if the Court grants FDA's motion for a minimum of a six-month (and what would likely turn out to be a year-plus) stay. As Plaintiff has indicated from its earliest filings in this case, until the entire body of documents provided by Pfizer to FDA are made available, an appropriate independent analysis by independent scientists who are members of Plaintiff is not possible.[5] It is analogous to a 1,000-piece puzzle where FDA refuses to hand over the remaining 10 pieces in a timely fashion and instead simply wants to celebrate itself for the 990 pieces that it did provide. Like puzzle pieces, however, the Pfizer COVID-19 vaccine data FDA provided so far is near useless until *all* of it is produced. Unlike a puzzle, however, the timeliness of the production of this data does matter.

Nearly three-and-a-half years after initially requesting this information, and nearly three years since the Court's order setting a production schedule, Plaintiff's members still cannot conduct an independent analysis. Should FDA's request be granted, it will delay any independent analysis for *at least* another year, which means the American public, yet again, will be delayed in knowing what our federal government saw and knew during the pandemic. As the Court well knows, justice delayed is justice denied: "Congress has long recognized that information is often useful only if it is timely and that, therefore excessive delay by the agency in its response is often tantamount to denial." *PHMPT I*, Dkt. 35 at 2 (internal quotation marks omitted). By any measure, FDA has caused excessive delay in providing the requested information to the public—information which FDA does not dispute must be disclosed—and the party that stands to be harmed by this delay is not just Plaintiff; it is all Americans. FDA has made clear by the history of this case that

[5] *See* Dkt. 94 at 15, n. 16 and n. 17.

it will not produce the requested data until compelled to do so by a court. FDA has also shown that while it says it cannot handle large production rates, when ordered to do so, it makes it happen. The purpose of FOIA will be completely obliterated if this Court grants FDA until the end of the *PHMPT II* production before it has to even make an effort to begin to fulfill the instant three-and-a-half-year-old request. Therefore, this factor weighs against the grant of a stay.

With respect to the second *Landis* factor, FDA, as ever, emphasizes the "hardship" it will endure if forced to produce the requested documents on the Court-ordered schedule. But whatever "hardship" results from the production of these crucial documents, it should not be borne by Plaintiff or the American people, who have had no hand in causing it. Moreover, while FDA engages in a protracted soliloquy about the "triaging [of] its limited resources" and its need to work "at full capacity to address the extraordinary workload," the fact is that a review of the documents provided so far reveals FDA's redactions have not been extensive. Specifically, out of the 1,200,874 pages FDA has produced so far, less than 329,932—or approximately 27.5%—contain redactions. Even more significantly, approximately 80% of the documents with redactions contain non-complex (b)(6) redactions of items such as names, dates of birth, etc.—items that are easily located by using artificial intelligence. If this same pattern applies to the EUA file—and there is no reason to believe it will not—this only further cuts against FDA's near-hysterical claims of hardship and, accordingly, indicates that this factor does not weigh in favor of a stay.

The final *Landis* factor weighs in favor of granting a stay only when the orderly course of justice will be advanced through the simplifying of issues, proof, and questions of law. *See Landis*, 299 U.S. at 255. A stay will do none of these things here. Once again, this case arrived on the Court's docket over 1,200 days (or nearly 3 years, 4 months) ago, on September 16, 2021. Should FDA's instant Motion be granted, this case is all but guaranteed to remain on the Court's docket

for at least another year. This is because, instead of asking the Court to stay this matter for a specific period of time, FDA instead asks the Court to: "stay the June deadline until the conclusion of production in *PHMPT II*," which as of now is June 30, 2025. (Dkt. 104 at 5.) It then proposes, 14 days after production is complete, to "file a joint status report advising this Court and setting forth a proposed processing schedule for the responsive EUA file at a rate of 55,000 pages per month." *Id.* As FDA is surely aware, Plaintiff will likely need to file challenges to redactions and withheld documents and, will very likely raise adequacy of search issues in *PHMPT II* if FDA also withheld EUA file records in that case; consequently, the true "conclusion of production in *PHMPT II*," is not likely to be until months after June 30, 2025. Nonetheless, FDA goes even further, and proposes that when the agency finally starts producing the EUA files which should have already been produced, that it do so at a "rate of 55,000 pages per month." *Id.* Thus, should FDA's request be granted, realistically, it is unlikely that Plaintiff will receive any documents before August 2025 (and this is assuming FDA does *not* intend to wait until redaction, withholding, and adequacy of search issues are dealt with in *PHMPT II*) and, at a rate of 55,000 pages per month, Plaintiffs would not have the complete EUA file (which FDA now states contains "at a minimum, 589,600 pages") until July 2026, earliest. This will be almost five years after the initial request for these records. In reality, the timeline will be much longer. This in no way serves the interests of judicial economy.

But beyond the problem this poses to judicial economy and beyond even the obvious fact that, under FDA's proposed schedule, this information is likely to be all but useless by the time Plaintiff, and the American public, receive it years from now, there is an additional reason to deny FDA's requested stay: it would set a very poor precedent. In its brief, FDA references "promot[ing] judicial economy by discouraging a further onslaught of FOIA litigation." (Dkt. 104 at 25.) Plaintiff notes that, to its knowledge, the **only** thing that has ever actually caused FDA to hire more

individuals to handle its FOIA obligations and to address its backlog has been litigation—specifically, orders from this Court in this case and *PHMPT II*—which, ultimately, benefits all FOIA requesters.[6] Consider the contrary: If an agency like FDA can improperly withhold responsive documents, forcing litigation and briefing, and can then seek a stay on its obligation to produce those documents after the Court agrees they are responsive and were wrongly withheld, it will set a terrible precedent and create for agencies yet another delay tactic, dragging out FOIA litigations everywhere. The granting of a stay in this case will only encourage this type of misbehavior which is unequivocally not in the interest of judicial economy for this court or any other.

Simply stated, there is nothing to warrant a halt to this litigation, especially for the length requested by FDA, and the result of halting it would be a year-long—if not, multi-year-long—delay, production of stale data, and bad precedent that will embolden defiant agencies. Therefore, this factor, too, weighs against the grant of a stay.

Should the Court consider any alteration of its judgment, which Plaintiff vehemently opposes for the reasons above, Plaintiff respectfully requests that a specific end date of a production be ordered instead of a joint status report fourteen days after completion of production

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[6] Relatedly, FDA suggests that a stay is proper because this litigation is being used to "jump[] the queue" ahead of other requests simply because Plaintiff has taken advantage of the legal right (available to all requesters) to litigate FDA's violation of FOIA. As is discussed above, however, FDA's FOIA processing is notoriously slow and backlogged and in almost every event violates the time limits established by FOIA. Short of requestors filing lawsuits, almost nothing is produced in any reasonably timely fashion, especially from CBER. The fact that the instant litigation has forced FDA to direct its resources to FOIA, hiring more people and increasing its FOIA budget, in order to produce information, means that **every** requester wins. While Plaintiff's litigation may mean that it, along with all Americans, will get these specific records a bit faster—and for good reason as set forth in prior briefing—it also pushes FDA's FOIA conveyor belt to move faster in a way that ensures every FOIA requester benefits.

in *PHMPT II*. This would enable FDA to start processing records in ample time to meet that deadline. If the Court does not order a specific end date for production and instead orders a start date, regardless of what that start date is, Plaintiff asks the Court to grant FDA a maximum of six months to produce all of the remaining documents. This would result in a production rate less than the 112,000 – 380,890 pages FDA has been producing per month in *PHMPT II* since January 2024, when calculated based on FDA's current representation that the EUA file contains at least 589,600 pages.[7]

**CONCLUSION**

For each of the foregoing reasons, the Court should deny FDA's Motion to Alter or Amend Judgment, and uphold its prior decision, ordering FDA to disclose the non-exempt portions of all remaining responsive records including the EUA file with production to be complete no later than June 30, 2025.

Dated: January 9, 2025

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[7] Should the Court determine that altering the deadline is appropriate and a delay of the completion of the production results, Plaintiff may seek the right to move for interim attorneys' fees and costs given that counsel has been litigating this matter for more than three years with no end in sight. If the Court agrees that such fees are appropriate and awards them to Plaintiff, the Court may consider issuing a finding that "agency personnel acted arbitrarily or capriciously with respect to the withholding," prompting the Office Special Counsel to initiate a proceeding to determine whether disciplinary action is warranted. 5 U.S.C. § 552(a)(4)(F)(i). In such an investigation, "if an agency has a practice of unlawfully withholding the disclosure of responsive records…it will be subject to an injunction barring the practice." *Judicial Watch, Inc. v. Dep't of Homeland Sec.*, 895 F.3d 770, 799 (2018).

**CERTIFICATE OF SERVICE**

I hereby certify that on January 9, 2025, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

*/s/ Elizabeth A. Brehm*
Elizabeth A. Brehm