UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN SOLOMON,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 24-0572 (RBW)

**DEFENDANT'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT ON ITS DENIAL OF PLAINTIFF'S REQUEST FOR EXPEDITED PROCESSING**

Pursuant to Federal Rule of Civil Procedure 56, Defendant U.S. Department of Health and Human Services hereby cross-moves for partial summary judgment on Plaintiff's claim for expedited processing of his FOIA requests. The reasons for this cross-motion are set forth in the accompanying Memorandum in Support of Defendant's Cross-Motion for Partial Summary Judgment on Its Denial of Plaintiff's Request for Expedited Processing, Opposition to Plaintiff's Motion for Partial Summary Judgment, and Reply in Support of Defendant's Motion to Stay; Defendant's Response to Plaintiff's Statement of Material Facts; and Defendant's Statement of Additional Material Facts Not Genuinely in Dispute. Pursuant to Local Civil Rule 7(m), Plaintiff opposes this motion.

Date: September 20, 2024
Washington, DC

Respectfully submitted,

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**MEMORANDUM IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT ON ITS DENIAL OF PLAINTIFF'S REQUEST FOR EXPEDITED PROCESSING, OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF ITS MOTION TO STAY**

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## INTRODUCTION

Defendant United States Department of Health and Human Services (the "Department"), on behalf of its components, the Food and Drug Administration ("FDA") and Centers for Disease Control and Prevention ("CDC"), respectfully submits this memorandum in support of its cross-motion for summary judgment on expedited processing, in opposition to Plaintiff John Solomon's motion for partial summary judgment on that issue, and as its reply in support of its stay motion. Put simply, this case is not a dispute over the safety of COVID-19 vaccines, but whether Plaintiff has met his burden of demonstrating that he is entitled to expedited processing under the plain language of the Freedom of Information Act ("FOIA") and FDA's implementing regulations, and whether a stay is warranted given the circumstances confronting FDA's Center for Biologics Evaluation and Research (the "Center") FOIA office. The answer to the first question is a resounding "no," and the answer to the second question is an equally resounding "yes." Plaintiff has not met his burden because he did not comply with the requirements for submitting a proper request for expedited processing and failed to show a "compelling need" for the information he seeks. And the Department has shown that the circumstances facing FDA necessitate entry of a stay, as every court in this district that has ruled on the issue has recognized.

Additionally, even if FDA had granted Plaintiff's request for expedited processing, FOIA and FDA regulations provide for processing "as soon as practicable"; and as the stay motion and supporting declarations attest (and yet one more district court recently determined), the current situation facing the Center's FOIA office makes it impractical for it to process any complex requests for at least the next 18 months. Nothing in Plaintiff's opposition refutes the Department's well-documented need for a stay, either under 5 U.S.C. § 552(a)(6)(C) for demonstrating exceptional circumstances and due diligence or under *Landis v. North American Co.*, 299 U.S. 248 (1936), to protect the Department from serious hardship if a stay were not granted.

## I. BACKGROUND RELATING TO PARTIAL SUMMARY JUDGMENT

### A. Procedural Background

On January 2, 2024, Plaintiff submitted identical FOIA requests to FDA and the CDC seeking "all records of updates and corrections relating to COVID-19 Vaccinations-such as formal diagnoses, recovery, or death-that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database." Def.'s Ex. 1 hereto (Plaintiff's FOIA request to FDA); Def.'s Ex. 2 hereto (Plaintiff's FOIA request to the CDC). VAERS is a national early warning system co-managed by the CDC and FDA that was established to detect possible safety problems in U.S.-licensed vaccines. *See* About VAERS, https://vaers.hhs.gov/about.html (last accessed Sept. 18, 2024). Anyone can report an adverse event to VAERS, and licensed vaccine manufacturers are required to report adverse events associated with use of their vaccine under 21 C.F.R. § 600.80, regardless of whether they consider the events to be related to the product. *Id.* "VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. It is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern." *Id.*

In his FOIA requests, Plaintiff asserted that the "data" he was seeking "has enormous value to the public's understanding of vaccine safety and efficacy and how the government surveils for safety signals." Def.'s Ex. 1. He requested expedited processing of both requests because "the matter is one of widespread and exceptional media interest, and I am primarily engaged in the dissemination of information to the public. Expedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and

uncorrected version and need the requested information to make informed medical decisions." *Id.* While Plaintiff emphasized the importance of the information he was seeking, he did not raise or specify any particular *urgency* underlying his request or certify any of his assertions "to be true and correct to the best of [his] knowledge and belief," as required by FOIA. 5 U.S.C. § 552(a)(6)(E)(vi); 21 C.F.R. § 20.44(d).

On January 3, 2024, the CDC acknowledged Plaintiff's FOIA request. In the acknowledgment letter, CDC granted the fee waiver because it considered Plaintiff a "News media requester" but denied the request for expedited processing because he "failed to show that there is an imminent threat to the life or physical safety of an individual." Def.'s Ex. 3 hereto.

On January 3, 2024, FDA also acknowledged Plaintiff's FOIA request to it. Def.'s Ex. 4 hereto. On January 8, 2024, it denied Plaintiff's request for expedited processing, stating:

> The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."
>
> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

Def.'s Ex. 5 hereto.

On January 18, 2024, Plaintiff, through counsel, appealed the CDC's denial of his expedited processing request to the Department, arguing that the CDC had applied the wrong

standard in rejecting his request, and not the one applicable to a "person primarily engaged in disseminating information." Def.'s Ex. 6 hereto at 2. Plaintiff did not appeal FDA's determination that he did not meet the criteria for expedited processing.

On February 8, 2024, the Department informed Plaintiff that the CDC had determined that Plaintiff's FOIA request fell under FDA's jurisdiction, that the CDC had referred the request to FDA and administratively closed the request to it, and for those reasons Plaintiff's request for expedited processing by CDC and his appeal from CDC's denial were moot. Def.'s Ex. 7 hereto.

**B. Requests For Expedited Processing**

Agencies ordinarily process FOIA requests for agency records on a first-in, first-out basis. In 1996, Congress amended FOIA to provide for "expedited processing" of certain categories of requests. *See* Electronic Freedom of Information Act Amendments of 1996, Pub. L. No. 104-231, § 8, 110 Stat. 3048 (codified at 5 U.S.C. § 552(a)(6)(E)) ("EFOIA"). When granted, an agency processes the request "as soon as practicable." *Id.* § 552(a)(6)(E)(iii); *see* 21 C.F.R. § 20.44(f); ECF No. 10-2, Burk Decl. ¶ 12 This generally means the request moves to the front of an agency processing queue, ahead of requests filed previously by other persons who did not request or do not qualify for expedited processing, but subject to court orders imposing deadlines, whether in other FOIA cases or in discovery, or requests for information from Congress. ECF No. 10-2, Burk Decl. ¶ 12. Congress also directed agencies to promulgate regulations providing for expedited processing of requests for records. Specifically, Congress directed agencies to enact regulations providing for expedited processing (i) "in cases in which the person requesting the records demonstrates a compelling need," 5 U.S.C. § 552(a)(6)(E)(i)(I); and (ii) "in other cases determined by the agency." *Id.* § 552(a)(6)(E)(i)(II).

"Compelling need" is defined to mean: (1) "that a failure to obtain requested records on an expedited basis . . . could reasonably be expected to pose an imminent threat to the life or physical

safety of an individual," or (2) "[w]ith respect to a request made by a person primarily engaged in disseminating information," there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II); *see also* 21 C.F.R. § 20.44(a); 45 C.F.R. § 5.27(b). This urgency must be certified to by the requester. 5 U.S.C. § 552(a)(6)(E)(vi).

Similarly, under FDA's implementing FOIA regulations, a requester must "demonstrate a compelling need" to obtain expedited processing. 21 C.F.R. § 20.44(a). Specifically, "[w]ith respect to a request made by a person primarily engaged in disseminating information," there must be "a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." *Id.* § 20.44(a)(2). And this in turn requires the requester to "demonstrate" that:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; . . . and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

*Id*. § 20.44(c)(1)-(3).

In addition, "[e]ach such request shall include information that demonstrates a reasonable basis for concluding that a compelling need exists . . . and a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief"; and "[a]ny statements made in support of a request for expedited processing are subject to the False Reports to the Government Act (18 U.S.C. 1001)." *Id.* § 20.44(d).

## II. DEFENDANT'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFF'S CLAIM FOR EXPEDITED PROCESSING OF HIS FOIA REQUEST SHOULD BE GRANTED AND PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT SHOULD BE DENIED

### A. Legal Standards Governing Summary Judgment Proceedings

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine if a reasonable factfinder could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it might affect the outcome of the suit under the governing law. *Id.* Although all inferences are taken in a light most favorable to the nonmoving party, a party opposing summary judgment may not rest on allegations or denials from its pleadings but "must set forth specific facts showing that there is a genuine issue for trial." *Id.* at 255-56.

In a FOIA case, summary judgment may be granted "on the basis of agency affidavits if they contain reasonable specificity of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith." *Evans v. Fed. Bureau of Prisons*, 951 F.3d 578, 584 (D.C. Cir. 2020) (citation omitted).

### B. Legal Standard Governing Expedited Processing

In enacting EFOIA, Congress specified that the expedited processing categories should be "narrowly applied." *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001) (quoting H.R. Rep. No. 104-795, at 26, 1996 U.S.C.C.A.N. 3448, 3469 (1996)). As the D.C. Circuit has explained:[1]

[1] Courts often rely on D.C. Circuit case law concerning FOIA, as it is "the federal appellate court with the most experience in this field." *Cameron Corp. v. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

> Congress' rationale for a narrow application is clear: "Given the finite resources generally available for fulfilling FOIA requests, unduly generous use of the expedited processing procedure would unfairly disadvantage other requestors who do not qualify for its treatment." . . . Indeed, an unduly generous approach would also disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none.

*Id.* at 307 n.7 (quoting H.R. Rep. No. 104-795, at 26); *see also Children's Health Def. v. CDC*, Civ. A. No. 23-0431 (TNM), 2024 WL 3521593, at *5 (D.D.C. July 24, 2024) ("And forcing FDA to move 512 documents to the head of the line would encourage every well-heeled FOIA requester to litigate for a fast pass, all to the detriment of every other requester in the queue."); *Energy Policy Advocates v. U.S. Dep't of Interior*, Civ. A. No. 21-1247 (JEB), 2021 WL 4306079, at *4 (D.D.C. Sept. 22, 2021) ("In sum, there is no basis for offering Plaintiff special treatment not available to similarly situated FOIA requesters, most of whom are patiently waiting in line."). Likewise, Department of Justice guidance advises agencies to "carefully" assess the merits of expedited processing requests "[b]ecause the granting of a request for expedition necessarily works to the direct disadvantage of other FOIA requesters." U.S. Dep't of Justice, FOIA Update: OIP Guidance: When to Expedite FOIA Requests (Jan. 1, 1983), https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

Further, while the burden is on the agency to justify any withholding of records under claimed FOIA exemptions, 5 U.S.C. § 552(a)(4)(B), the burden is on the requester to "demonstrate[] a compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(i); *see also Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 122 (D.D.C. 2013) (explaining that "[t]he requestor bears the burden of proof" in expedited processing cases); *Al-Fayed*, 254 F.3d at 305 n.4 (same) (citing 5 U.S.C. § 552(a)(6)(E)(i)(I) and H.R. Rep. No. 104-795, at 25). And, as noted above, to do so the requester must "demonstrate" a compelling need by a statement certified "to

be true and correct to the best of such person's knowledge and belief." 5 U.S.C. § 552(a)(6)(E)(vi); 21 C.F.R. § 20.44(d) (same); 45 C.F.R. § 5.27(a) (same).

Finally, while denial of a request for expedited processing is subject to judicial review, such judicial review "shall be based on the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(I)(iii); *see also, e.g., Am. Oversight v. U.S. Dep't of Justice*, 292 F. Supp. 2d 501, 505-506 (D.D.C. 2018). A decision denying expedited processing for failure to establish "compelling need" under § 552(a)(6)(E)(i) is reviewed *de novo*. *See Al-Fayed*, 254 F.3d at 307-08.

### C. Plaintiff is Not Entitled to Expedited Processing Because It Failed to Demonstrate a "Compelling Need"

#### 1. The record before the agency at the time of its expedited processing decision is exceedingly narrow

FDA properly denied Plaintiff's request for expedited processing "based on the record before the agency at the time of [its] determination." 5 U.S.C. § 552(a)(6)I(iii). Plaintiff does not dispute that he failed to demonstrate a compelling need during the administrative process before FDA based on "an imminent threat to the life or physical safety of an individual." *See* Def.'s Ex. 1 (Plaintiff's FOIA Request to FDA); Def.'s Ex. 2 (Plaintiff's FOIA request to the CDC). Indeed, that was the basis of the CDC's denial of his request for expedited processing, a decision he appealed to the Department. *See* Def.'s Ex. 6 at 2 (relying on 5 U.S.C. § 552(a)(6)(E)(i)(I)).[2] But Plaintiff did not appeal FDA's January 8, 2024 determination, and the record before the agency at the time of FDS's determination were only three documents: Plaintiff's FOIA request; FDA's

[2] As discussed above, the Department dismissed Plaintiff's appeal of the CDC's denial of his expedited processing request as moot because the FOIA request fell under FDA's jurisdiction, and CDC referred the request to FDA and administratively closed its file. Plaintiff has not challenged that determination.

acknowledgment letter; and FDA's expedited processing determination letter. As the court explained in *Legal Eagle*, "Congress has made clear that judicial review of agency denials of requests for expedited processing must be 'based on the record before the agency at the time of the determination,' 5 U.S.C. § 552(a)(6)(E)(iii), not on 'commonly-known information' that the agency should have considered in addition to the record." *Legal Eagle, LLC v. Nat'l Sec. Council Recs. Access & Info. Sec. Mgmt. Directorate*, Civ. A. No. 20-1732 (RC), 2021 WL 1061222, at *6 (D.D.C. Mar. 18, 2021) (denying plaintiff's request for expedited processing of records regarding National Security Advisor John Bolton); *see also Energy Policy Advocates*, 2021 WL 4306079, at *4 (judicial review of such agency denials must be based on record before agency at time of decision, "not on outside information.").

**2. Plaintiff failed in its burden to demonstrate urgency**

Plaintiff's sole basis for requesting expedited processing is in his FOIA request. Apart from establishing his role as a member of the media "engaged in the dissemination of information to the public," he asserted that "the matter [data records in the Vaccine Adverse Event Reporting System (VAERS) relating to COVID-19 vaccines that are not in the public VAERS database] is one of widespread and exceptional media interest"; and "[e]xpedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and uncorrected version and need the requested information to make informed medical decisions." Def.'s Ex. 1. These statements may explain why Plaintiff was seeking the information and requesting a waiver of fees[3] but does not even purport to address the statutory and regulatory

[3] So, too, Plaintiff's earlier statement in his FOIA request, that "[t]his data has enormous value to the public's understanding of vaccine safety and efficacy and how the government surveils for safety signals," may explain why he wanted to disseminate the data but not why his doing so was "urgent." Ex. 1.

requirement that he demonstrate "an urgency to inform the public concerning actual or alleged Federal Government activity" under 5 U.S.C. § 552(a)(6)(E)(v)(II).

In determining whether requesters have demonstrated an "urgency" to inform, and hence a "compelling need," courts consider at least three factors: "(1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity." *Al-Fayed*, 254 F.3d at 310.

As FDA demonstrated in its Memorandum in Support of its Motion to Stay ("Def.'s Mem."), ECF No. 10-1, it voluntarily and proactively has made vast amounts of information about COVID-19 vaccines and related FDA activities available to the public on its website, and it continues to do so. *See* Def.'s Mem. at 20-21, Moderna's COVID-19 Vaccines, https://www.fda.gov/vaccines-blood-biologics/spikevax (last updated Sept. 21, 2023); Comirnaty, https://www.fda.gov/vaccines-bloodbiologics/comirnaty (last updated Dec. 7, 2023); *see also* https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccineshttps://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines (last visited Sep. 5, 2024). The fact that people may have differing views about the safety or efficacy of certain FDA-regulated products does not of itself create "urgency" within the meaning of the expedited processing standard – especially in light of the amount of information published on FDA's website about COVID-19 vaccines. FDA approves medical products regularly in the course of agency business and it is not unheard of for those approvals to be the subject of controversy and disagreement. Such a situation, without more, cannot be deemed to create an urgent need for the agency to expedite its search for, review, and processing of specific

records sought in a particular request, especially when the agency routinely publishes summaries of safety and efficacy information on its website and makes additional information available in VAERS. If unsupported assertions such as Plaintiff's became the standard for expedited processing, a great number of FDA's FOIA requests would qualify, and requesters with non-expedited requests would have their wait times extended – possibly significantly.

"Compelling need" and "urgency" as used in FOIA convey Congress' view that individuals in particular, or the public at large, are at imminent risk of harm if the information sought is not disclosed quickly. *See* 5 U.S.C. § 552(a)(6)(E)(v)(I) and (II); Cambridge Dictionary Online, URGENCY | definition in the Cambridge English Dictionary (last accessed Sept. 18, 2024) (the quality of being very important and needing attention immediately"); Urgency - Definition, Meaning & Synonyms | Vocabulary.com (last accessed Sept. 18, 2024) (requiring speedy action; "comes from the Latin *urgere*, which means 'press, or drive,'"; a pressing issue that requires a quick response); Compelling - Definition, Meaning & Synonyms | Vocabulary.com (last accessed Sept. 18, 2024) ("to drive or force into action"; "tending to persuade by forcefulness of argument"). Indeed, FDA's implementing regulations make this explicit. They require a request for expedited processing under 21 C.F.R. § 20.44(a)(2), as was Plaintiff's FOIA request to FDA, to "demonstrate" not only "an urgent need for the requested information" but that the information "has a particular value that will be lost if not obtained and disseminated quickly," 21 C.F.R. § 20.44(c), and to do so with "information that demonstrates a reasonable basis for concluding that a compelling need exists," attested to by "a certification that the information provided in the request is true and correct," *id.* § 20.44(d).

The analysis in *New York Times Co. v. Defense Health Agency*, Civ. A. No. 21-0566 (BAH), 2021 WL 1614817 (D.D.C. Apr. 25, 2021), although involving a motion for preliminary

injunction and not a request for expedited processing, is instructive with respect to application of the compelling need standard, and Plaintiff's failure to meet it, here.[4] In that case, the plaintiff, whose FOIA request sought extensive information about COVID-19 vaccines, moved for a preliminary injunction to force expedited production of the records at issue. *Id.* at *1. The court denied the motion for several reasons, many of which are pertinent here. For example, the court rejected the plaintiff's argument that safety concerns created an exigency:

> To support its claimed irreparable harm, plaintiff describes a parade of harms from delay in releasing the four requested data sets, contending that such delay could "pose an imminent threat to the life and safety of individuals in the United States," by diminishing the strength of public oversight, preventing the public's access to accurate reporting about the efficacy of the vaccine and the equity of the vaccine rollout, and depriving public health officials of information that would help them "develop appropriate responses to . . . inequities" and stem "preventable deaths[.]" While attention-grabbing, these purported harms to oversight, vaccination hesitancy and equitable vaccine distribution, which are all important to public health generally, are all premised on theoretical injuries, with no assurance that the remedy for these cited public health ills is production of the datasets requested in plaintiff's FOIA requests. Such "bare allegations of what is likely to occur are of no value since the court must decide whether the harm will in fact occur," and whether "the alleged harm will directly" flow from the occurrence movant seeks to compel or enjoin.

*Id.* at *8 (citations omitted). The court also dismissed as hyperbole the plaintiff's claim that, without prompt production of the requested data sets, the public would be left without a basis to form an opinion about whether to receive the vaccine, noting that any purported link between the requested data sets—even with plaintiff's subsequent handling, analysis and reporting on that information—and the population's hesitancy about vaccines was, at best, speculative. *Id.* at 9.

Further, the plaintiff in *New York Times*, like Plaintiff in this case, never provided any

[4] *See, e.g.*, *N.Y. Times*, 2021 WL 1614817, at *4 n.6 ("To the degree plaintiff uses its urgency arguments to show irreparable harm, by claiming that "delaying a response would compromise a significant recognized interest . . . [namely,] the health of the public," these arguments are considered [in Part B discussing irreparable harm].").

information shedding light on the date by when the records needed to be produced to avoid the posited harm. *Id.* at 8; *see also*, 21 C.F.R. § 20.44(c)(2) (request for expedited processing "must demonstrate . . . an urgent need for the requested information and that it has a particular value [that] will be lost if not obtained and disseminated quickly[.]"). The Court found that this was further grounds to deny expedited production:

> Absent a critical need for records at a scheduled or imminent event, however, preliminary injunctive relief to expedite production of records in FOIA cases is generally denied. . . . Plaintiff's FOIA requests seek records that will be indisputably valuable in informing the public about how the federal government functioned in preserving public health during a global pandemic, but these records are not "time-sensitive" in the sense of losing value vis-à-vis any date certain. As the government observes, "Plaintiff has not shown that there is any particular time limit on the usefulness of that information; public critiques of how the government handled vaccination, for example, do not have an expiration date, and Plaintiff has not identified any future date at which COVID vaccines and their distribution and effects will not be of interest to the public."

*Id.* at *8; *see Al-Fayed*, 254 F.3d at 311 (plaintiffs failed to demonstrate any "significant adverse consequence" that would result from denial of their request for expedited processing); *Energy Policy Advocates*, 2021 WL 4306079, at *4 ("While the request may suggest that the requested information is *important* in some sense, it fails to identify any specific reason to conclude that obtaining the requested documents is *time sensitive*." (emphasis in original)); *Heritage Found. v. Env't Prot. Agency*, Civ. A. No. 23-0748 (JEB), 2023 WL 2954418, at *4 (D.D.C. Apr. 14, 2023) (finding plaintiff failed to show delay would compromise a significant recognized interest because, among other things, plaintiff did not identify a specific end-date).

Finally, when analyzing the balance of equities and public interest in the records sought, the court recognized that an injunction, like a grant of expedited processing, would "impose undue hardship on similarly situated FOIA requesters, who are depending on, and adhering to, regular administrative FOIA record production processes to obtain information important to them," including requesters also seeking information relating to the COVID pandemic." *Id.* at *10

(citations omitted); *see also Energy Policy Advocates*, 2021 WL 4306079, at *4 ("no basis for offering Plaintiff special treatment not available to similarly situated FOIA requesters, most of whom are patiently waiting in line").

In sum, based on the meager record before FDA at the time of its decision, Plaintiff wholly failed to demonstrate a compelling need that would entitle him to expedited processing. And it bears noting that, even if Plaintiff had demonstrated a compelling need, it would mean only that processing of his FOIA request would take place "as soon as practicable." As the stay motion and supporting declarations attest (and yet one more district court recently determined),[5] the current situation facing the Center's FOIA office makes it impractical for it to process any complex requests for at least the next 18 months.

**3. Plaintiff did not certify to the truth of his assertions**

Plaintiff's FOIA request does not contain a certification attesting to his "knowledge and belief" that the information provided to demonstrate his compelling need "is true and correct." 21 C.F.R. § 20.44(d). The importance of this certification cannot be underestimated. Indeed, it is evidenced by the requirement that a FOIA requester certify to the facts underlying its request with the express caution that the certification is "subject to the False Reports to the Government Act (18 U.S.C. 1001)." 21 C.F.R. § 20.44(d). In addition to all the reasons set forth above, Plaintiff's failure to include a certification in and of itself is fatal to his motion for partial summary judgment.

**4. Plaintiff's counter arguments do not withstand scrutiny**

Plaintiff's contention that "[c]ourts may consider evidence from outside the record that was before the agency when reviewing denials of expedited processing," Pl.'s Opp'n at 4 n.1, is

[5] Min. Order, *Informed Consent Action Network v. Food and Drug Admin.*, Civ. A. No. 23-3675 (JMC) (D.D.C. Sept. 4, 2024) (granting FDA's motion to stay for six months with a joint status report update at the end of that period).

nonsensical and irrelevant.[6] It is nonsensical because information, if "before the agency" at the time of decision, is part of the record. 5 U.S.C. § 552(a)(6)(E)(iii). It is irrelevant if an appeal of a denial of expedited processing was, as here, never taken, the evidence is before a different agency (like the CDC), or the appeal of a denial is moot (as with CDC). Indeed, as demonstrated above, the "record before the agency" does not include even "'commonly-known information'" that is "outside the record," *Legal Eagle*, 2021 WL 1061222, at *6, or other "outside information," *Energy Policy Advocates*, 2021 WL 4306079, at *4.

Thus, Plaintiff's reliance on "report[s] that CDC and FDA do not consistently obtain updates and corrections after the initial reports, and . . . do not make the updates and corrections available to the public," Pl.'s Opp'n at 5, is misplaced, as is his reliance on the Congressional hearings it cites addressing "America's vaccine safety systems, including the adequacy of the VAERS dataset." Pl.'s Opp'n at 8, 13. These reports and hearings may reflect the reason for his interest in the information, but they are not in the record and, moreover, say nothing about urgency, lost value if the information became stale, or other "significant adverse consequence" if the records sought are not produced by a date certain. *Al-Fayed*, 254 F.3d at 311 (plaintiffs failed to demonstrate "significant adverse consequence" that would result if expedited processing request were denied); *Energy Policy Advocates*, 2021 WL 4306079, at *4 (request may suggest importance

[6] It bears noting that the court in *Treatment Action Group v. Food and Drug Admin.*, Civ. A. No. 15-0976, 2016 WL 5171987, at *4 (D. Conn. Sept. 10, 2016), which Plaintiff cites in support of this proposition, denied the plaintiff's motion for summary judgment regarding its entitlement to expedited processing and granted FDA's cross-motion for summary judgment on that issue. Although maintaining the "equitable powers" to consider matters outside the record before the agency, such as new justifications that the requester could not have raised at the time of submission of its FOIA request, it declined to do so "because of the explicit limitations of the statute." *Id.* at 4-5.

of requested information but provides no specific basis to conclude that obtaining the requested documents is "*time sensitive*." (emphasis in original)).

Plaintiff's motion for partial summary judgment, accordingly, must be denied.

## III. THE COURT SHOULD GRANT A STAY UNDER 5 U.S.C. § 552(a)(6)(C) AND *OPEN AMERICA*

This Court should grant Defendant'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 took and is continuing to take 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 woefully short.

### A. Exceptional Circumstances

Plaintiff's opposition to Defendant's Motion to Stay is premised on the Department being the entity responsible for the FOIA obligations at issue in this case, and in doing so, he confuses the Department with FDA. Thus, he argues that "**HHS is the responsible FOIA agency**" and impugns FDA as a "mere 'Operating Division[]' within HHS," ECF No. 14-1, Pl. Mem. at 10 (emphasis in original); asserts that "**HHS is not burdened with an unanticipated number of FOIA requests**" (emphasis in original), *id.* at 11; further asserts that "**HHS has adequate resources to process the requests,"** *id.* at 12 (emphasis in original); and concludes that "**HHS is neither exercising due diligence nor reducing its backlog**," *id.* at 13 (emphasis in original). This argument does not withstand scrutiny. Although the Department's regulations may define HHS as an "agency" and FDA as one of its "Operating Divisions," 45 U.S.C. § 3, those regulations require it to refer a request for an Operating Division's records to that division, *id.* § 5.25; and FOIA itself

defines "agency" to mean "each authority of the Government of the United States, ***whether or not it is within or subject to review by another agency***," 5 U.S.C. § 551(a) (emphasis added). FDA, accordingly, is unquestionably an "agency" within the meaning of FOIA.

If the historic, expedited production schedules in *PHMPT I* and *PHMPT II* do not constitute exceptional circumstances, nothing does. As the Burk Declaration explains (¶ 27), 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." 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*—and an average of more than 230,000 pages per month to meet the court's deadline in *PHMPT II*. Burk Decl. ¶ 6. 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.'s Opp'n at 15-16. Plaintiff, however, 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. And when considering whether an agency has shown "exceptional circumstances" under Section 552(a)(6)(C)(i), courts have appropriately framed their discussion around the burdens facing specific agency components. For example, in *Judicial Watch, Inc. v. U.S. National Archives & Records Admin.*, Civ. A. No. 07-1267 (JR), 2008 WL 11516011, at *1 (D.D.C. May 20, 2008), 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. 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's ability to carry 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 of FDA's Center for Veterinary Medicine, the small size of that center's FOIA staff, and its 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. *See* Kotler Decl. (Att. A), ¶¶ 15-17.

It would be manifestly inefficient to re-direct resources to the Center, as the Kotler Declaration explains. *See id.* At a broad level, FDA generally cannot reallocate staff from non-FOIA functions, with rare exceptions for short-term details, because 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, for example, from

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. ¶ 29 ("[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. *Id.* ¶ 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 the 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*. ¶ 9. FDA's resources to hire additional FOIA staff, both generally and in the Center, are limited because FOIA is an unfunded mandate, 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 Sept. 19, 2024).

Importantly, regardless of whether *PHMPT II*'s requirement to produce at least 180,000 pages per month is considered in the context of the Branch's workload or FDA's overall FOIA workload, it constitutes "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 the *PHMPT II* order and will need every resource available to it to be able to meet the production rate and deadline. *See* ECF No. 10-2, Burk Decl. ¶¶ 6, 35. 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.* ¶ 29; Kotler Decl. ¶ 18.

Plaintiff nonetheless argues that the Branch's current workload was predictable and therefore 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. Pl. Opp. at 16-19. Again, Plaintiff's arguments would have the Court ignore the magnitude of the productions required by the *PHMPT* orders and their cascade effect on the Branch's ability to process its backlog of requests. The increasing requests, moreover, counsel in favor of a stay. As FDA previously described, the backdrop of increasing FOIA requests and litigation in recent years exacerbated the burdens of the *PHMPT* orders. Burk Decl. ¶¶ 19-22. 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 in *PHMPT I*. 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." Transcript of Hearing, ECF No. 58 at 8:24-25, 9:1-23, *Pub. Health & Med. Profs. for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex. Feb. 7, 2022). The *PHMPT I* court called its own order "unprecedented." *Id.* at 9:19-24. And that order, in turn, did not make the later minimum 180,000 pages-per-month rate ordered in *PHMPT II* part of a "predictable" workload.

Finally, FDA did anticipate public interest in the COVID-19 vaccines. For that reason, it affirmatively made great amounts of information about the COVID-19 vaccines available to the public on its website. *See* Def.'s Mem. at 21, Moderna's COVID-19 Vaccines, https://www.fda.gov/vaccines-blood-biologics/spikevax (last updated Sept. 21, 2023); Comirnaty, https://www.fda.gov/vaccines-bloodbiologics/comirnaty (last updated Sep. 6, 2024); and https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines (last updated Aug.. 27, 2024). 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*.

Plaintiff's argument not only fails to account for actual circumstances but, 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, particularly given the end of production in *PHMPT I*. Pl. Opp.

at 12. Plaintiff does not explain how he reaches that conclusion, and his conjecture is refuted by the activities of the staff actually working on these requests. *See* Burk Decl. ¶ 33 (noting that "although these continued hiring and training efforts underscore the seriousness with which the agency takes its commitment to meeting its unprecedented FOIA obligations, they also cannot change the Center's workload capacity overnight or its need for a stay [of eighteen months] in this case").

"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.'" *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 59 (D.D.C. 2018) (quoting *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991)). And speculation is all Plaintiff has to offer here. Not only does he conveniently ignore the factors set forth in the Burk Declaration that go into the decision whether to seek a stay, Burk Decl. ¶ 28, but he also ignores evidence of CBER's careful application of these factors in other suits that did not demonstrate a need for FDA to seek a stay. *See, e.g.*, *Informed Consent Action Network v. FDA*, Civ. A. No. 22-3572 (CKK) (D.D.C.), filed November 23, 2022; *de Garay v. FDA*, Civ. A. No. 22-0512 (S.D. Ohio), filed September 3, 2022.

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* Def.'s Mem. at 15-18.

**B. FDA Is Exercising Due Diligence**

As described in the Burk Declaration (¶ 12), 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." *Compare* Def.'s Mem. at 18 (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)) *with* Pl. Opp. at 13-14 (describing the "lack of due diligence" as being exacerbated by the pandemic). 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* Def.'s Mem. at 18-21 (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 broadly that FDA is not exercising "due diligence" with respect to his FOIA requests in particular or with respect to FOIA requests submitted to FDA in general. *See* Pl. Opp. at 13-14.

With respect to Plaintiff's FOIA request in particular,[7] FDA reviewed it and determined it should be placed in the Center's Complex Track queue because the request is expected to require more processing time than requests in other queues. Def.'s Mem. at 10; Burk Decl. ¶ 34; *see id.* ¶ 12 (describing FOIA queues). If a stay is granted, Plaintiff's FOIA request will retain its place in the complex queue and be processed in accordance with the Branch's "first-in, first-out" process. *Id.* ¶¶ 18, 36; *see id.* ¶ 34 (noting that Plaintiff's requests are behind 477 and 478 earlier submitted requests pending in the Complex Track). 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.

[7] Although CDC referred Plaintiff's FOIA request to FDA, as noted above, it is identical to the one Plaintiff submitted to FDA. Accordingly, we refer to the FOIA request here in the singular.

*Id.* ¶¶ 18, 25, 36. 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.* ¶ 18. 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.* ¶¶ 18, 36. 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. *Id.* ¶ 18.

Accordingly, if a stay is entered in this case, Plaintiff's request will keep its place in the Complex Track queue, *id.* ¶ 36; and if the 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. By 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 with respect to Plaintiff's request.

Finally, FDA's extraordinary efforts to hire and train new employees and contractors since the *PHMPT I* production order issued defeat Plaintiff's contention that FDA is not exercising due diligence with respect to FOIA requests submitted to FDA in general. *Compare* Pl. Opp. at 16 *with* Burk Decl. ¶¶ 25, 28-30; Kotler Decl. (Att. A), ¶ 7. FDA's efforts to add to and maximize Branch resources go far beyond what is necessary to show due diligence. Ms. Kotler's Declaration refutes Plaintiff's claims regarding FDA's FOIA workload since the start of the pandemic. *See* Kotler Decl. (Att. A), ¶¶ 9-10 (describing FDA's increased FOIA COVID-related requests, increased

FOIA litigation, increased hiring, and specialized training efforts). And Plaintiff's argument that FDA should be required to divert resources from FOIA offices in other centers to show due diligence, Pl. Opp. at 17-18, 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. (Att. A), ¶ 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 and 4,706 at the end of fiscal year 2023. *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 of the "due diligence" needed for a stay under Section 552(a)(6)(C)(i). *See* Def.'s Mem. at 18-21.

Plaintiff argues that because FDA's workload was "predictable," it must show "reasonable progress in reducing its backlog" of pending FOIA requests, which Plaintiff claims FDA cannot do, given the increase in the number of pending FOIA requests in the Branch and FDA overall. Pl. Opp. at 17 (quoting *Open Am.*, 547 F.2d at 605) (internal quotation marks omitted). However, as explained above and in Defendant's Memorandum in support of its stay motion, 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. Def.'s Mem. at 12-13 (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

backlog. For example, the Branch's 55,000-page productions in *PHMPT I* and 180,000-page productions in *PHMPT II* represent a monthly volume of records that may be higher than what tens (or even hundreds) of other FOIA requests in the backlog collectively involve, yet the Branch can respond to only (those) two FOIA requests in the Complex Track queue. 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.

## IV. The Court Should Grant a Stay Under *Landis*

Plaintiff's arguments against a *Landis* stay are similarly 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. Def.'s Mem. at 15-16. FDA simply lacks the resources to search for, review, and release any responsive records at this time. Moreover, a stay will obviate the need for court oversight at a time when it is not feasible for FDA to even propose a production schedule, thereby promoting judicial economy. *Id*. at 16.

As shown above, Plaintiff has failed to articulate a specific need for or urgency concerning these records sufficient to demonstrate that he will be injured if the Court grants a stay. Plaintiff's claims that the records will contribute significantly to the public's understanding of the government's vaccine safety programs are unfounded. As discussed in Defendant's Memorandum, FDA has already made a substantial amount of COVID-19 vaccine-related information available through its public-facing website and previous FOIA disclosures. *See* Def.'s Mem. at 21-22; p. 4-8, *supra*. For example, the public can access the Action Packages for the Pfizer/BioNTech Comirnaty vaccine, 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 the vaccine, 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); Def.'s Mem. at 21-22 (describing information already disclosed to the public). The CDC similarly provides COVID-19 vaccine-related information on its website. 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.

Finally, Plaintiff argues that FDA's hardship without a stay does not outweigh the harm caused by delaying the release of the requested records because they "are critical to the health and safety of the American public." Pl. Opp. at 18. But Plaintiff appears to misunderstand the magnitude of the hardship faced by FDA. That hardship stems from responding to Plaintiff's FOIA requests while its contractors and regular staff are completely occupied with processing *PHMPT II* records. The end of *PHMPT I* did not represent a decrease in the Branch's FOIA workload but a significant increase, as the *PHMPT II* production ramped up to at least 180,000 pages per month (and at least 230,000 pages per month on average to meet the court's deadline). Burk Decl. ¶ 26; *see id.* ¶¶ 7, 25-26, 28-29, 32-33 (explaining the Branch's efforts to maximize its resources); *id.* ¶ 35 (stating that the Branch cannot concurrently produce records in this litigation while meeting its court-ordered obligations); Kotler Decl. (Att. A), ¶¶ 14, 18 (explaining limitations of hiring/funding). Regardless of the total amount of resources needed to complete production in this case, the Branch simply does not have any resources available, which is why it is seeking to stay this case (and other cases where appropriate). After the expiration of an eighteen-month stay, the

Branch will submit a status report updating the Court as to its progress in *PHMPT II* and will be better situated to confer with Plaintiff about a reasonable schedule for production of any records responsive to its FOIA requests.

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

* * *

## CONCLUSION

For the foregoing reasons and those set forth in Defendant's Memorandum in Support of its Motion to Stay, the Court should grant Defendant's Cross-motion for partial summary judgment, deny Plaintiff's motion, and grant the Department's Motion to Stay.

Date: September 20, 2024
Washington, DC

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN SOLOMON,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 24-0572 (RBW)

**DEFENDANT'S STATEMENT OF ADDITIONAL MATERIAL FACTS NOT GENUINELY IN DISPUTE AND RESPONSE TO PLAINTIFF'S STATEMENT OF MATERIAL FACTS AS TO WHICH IT CONTENDS THERE IS NO GENUINE ISSUE**

Pursuant to Rule 7(h) of the Civil Rules of the United States District Court for the District of Columbia ("LCvR"), Defendant United States Department of Health and Human Services ("Defendant" or "Department") submits this Statement of Additional Material Facts Not Genuinely in Dispute and Response to Plaintiff's separate Statement of Material Facts as to Which It Contends There is No Genuine Issue ("PSOF").

**DEFENDANT'S LCvR 7(h) STATEMENT OF ADDITIONAL MATERIAL FACTS NOT GENUINELY IN DISPUTE**

1. On January 2, 2024, Plaintiff submitted a FOIA request to FDA seeking "all records of updates and corrections relating to COVID-19 Vaccinations-such as formal diagnoses, recovery, or death-that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database." A true and correct copy of Plaintiff's FOIA request to FDA is attached as Def.'s Ex. 1 hereto.

2. On January 2, 2024, Plaintiff submitted an identical FOIA request to the CDC. A true and correct copy of Plaintiff's FOIA request to the CDC is attached as Def.'s Ex. 2 hereto.

3. In both of his FOIA requests, Plaintiff requested expedited processing because "the matter is one of widespread and exceptional media interest, and I am primarily engaged in the dissemination of information to the public. Expedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and uncorrected version and need the requested information to make informed medical decisions." Def.'s Exs. 1, 2.

4. On January 3, 2024, the CDC sent Plaintiff a letter acknowledging his FOIA request. In the acknowledgment letter, CDC granted the fee waiver because it considered Plaintiff a "'News media requester'" but denied the request for expedited processing because he "failed to show that there is an imminent threat to the life or physical safety of an individual." Ex. 3. A true and correct copy of the CDC's acknowledgment letter to the CDC is attached as Def.'s Ex. 3 hereto.

5. On January 3, 2024, FDA sent Plaintiff a letter acknowledging his FOIA request. A true and correct copy of FDA's letter acknowledging his FOIA request is attached as Def.'s Ex. 4 hereto.

6. On January 8, 2024, FDA denied Plaintiff's request for expedited processing. A true and correct copy of FDA's denial of Plaintiff's request for expedited processing is attached as Def.'s Ex. 5 hereto.

7. On January 18, 2024, Plaintiff, through counsel, appealed the CDC's denial of his expedited processing request to the Department. A true and correct copy of this appeal letter is attached as Def.'s Ex. 6 hereto.

8. Plaintiff did not appeal FDA's determination that he did not meet the criteria for expedited processing.

9. On February 8, 2024, the Department sent a letter to Plaintiff informing him that the CDC had determined his FOIA request fell under FDA's jurisdiction, that CDC had referred the request to FDA and administratively closed the request to it, and for those reasons his request for expedited processing by the CDC and his appeal from the CDC's denial, were moot. A true and correct copy of this letter is attached as Def.'s Ex. 7 hereto.

10. Plaintiff's FOIA requests did not contain "a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief." *See* Def.'s Exs. 1, 2.

11. Only Plaintiff's FOIA request to FDA and FDA's acknowledgment letter were before FDA at the time it denied Plaintiff's request for expedited processing.

12. VAERS a national early warning system co-managed by the CDC and FDA, which was established to detect possible safety problems in U.S.-licensed vaccines. About VAERS, https://vaers.hhs.gov/about.html (last accessed Sept. 18, 2024).

13. Anyone can report an adverse event to VAERS, but licensed vaccine manufacturers are required to report adverse events associated with use of their vaccine under 21 C.F.R. § 600.80, regardless of whether they consider the events to be related to the product. *Id.*

14. "VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. It is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern." *Id.*

**DEFENDANT'S LCvR 7(h) RESPONSE**
**TO PLAINTIFF'S STATEMENT OF MATERIAL FACTS**
**AS TO WHICH IT CONTENDS THERE IS NO GENUINE DISPUTE**

1. The Vaccine Adverse Event Reporting System (VAERS) "is a national early warning system to detect possible safety problems in U.S.-licensed vaccines." *About VAERS*, DEP'T OF HEALTH AND HUM. SERVS., https://vaers.hhs.gov/about.html.

**Defendant's response**: Not disputed.

2. "VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA)." *Id*.

**Defendant's response**: Not disputed.

3. "VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination." *Id*.

**Defendant's response**: Not disputed.

4. VAERS "is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." *Id*.

**Defendant's response**: Disputed. Plaintiff's quotation is incomplete. The full sentence states: "VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." *Id.*

5. "VAERS, is co-managed by CDC and FDA and serves as the nation's early warning system to detect possible safety signals for all U.S. approved and authorized vaccines." *Assessing America's Vaccine Safety Systems, Part 1: Hearing Before the Select Subcomm. on the Coronavirus Pandemic of the H. Comm. on Oversight and Accountability*, 118th Cong. (Feb. 15, 2024) (statement of Daniel Jernigan, Director, National Center for Emerging and Zoonotic Infectious Diseases, CDC) (available at https://bit.ly/4c5JZR8).

**Defendant's response**: The facts set forth in the quoted statement are not disputed but Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the

time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

6. "Under the emergency use authorizations for COVID-19 vaccines, healthcare professionals and manufacturers were required to report serious adverse events following vaccination to VAERS, even if the cause of the event is unknown. Serious events include, but are not limited to, death, hospitalization, disability, congenital anomaly, severe allergic reactions, and other neurological or immune conditions." *Id*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

7. "Individuals and their families are encouraged to also submit VAERS reports for any adverse event that occurs after vaccination." *Id.*

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

8. "After an adverse event is reported, the information is processed and sent to CDC and FDA." Assessing America's Vaccine Safety Systems, Part 1: Hearing Before the Select Subcomm. on the Coronavirus Pandemic of the H. Comm. on Oversight and Accountability, 118th Cong. (Feb. 15, 2024) (statement of Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, FDA) (available at https://bit.ly/3WhkM0l).

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

9. "CDC and FDA staff continually assess VAERS data for vaccine adverse event reports. This includes review of individual reports, aggregate analysis of VAERS data, and review of case series data when indicated for possible safety concerns. As VAERS reports are received, CDC and FDA staff monitor for potential vaccine safety concerns or unusual patterns of rare and serious adverse events." Statement of Jernigan, *supra*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

10. "If a serious adverse event is reported, VAERS staff from CDC and FDA can request additional information such as medical records, death certificates, or autopsy reports from the healthcare provider of record." *Id*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

11. "These efforts are particularly important for promoting vaccine confidence and improving outcomes for those who may experience a rare adverse event." *Id*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

12. "VAERS has proven to be vital in detecting both potential and actual safety issues and informing vaccine policy decisions that protect the health of the American public. It has helped identify notable COVID-19 vaccine safety concerns. For example, after VAERS detected an increase in rare, life-threatening allergic reactions just weeks after the first vaccines were authorized, CDC and FDA provided information and guidance to help prevent and manage these reactions. Just days after VAERS detected that six out of the more than six million patients who received the Janssen COVID-19 Vaccine had developed a rare and severe type of blood clot, CDC and FDA recommended pausing the use of that vaccine to better understand this adverse event. Another example of the utility of VAERS is the detection of myocarditis following the mRNA COVID-19 vaccines, which led CDC to provide advice to healthcare providers about the potential risk and to recommend that some people, primarily teen and young adult males, space out their vaccines." Statement of Marks, *supra*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

13. "Unfortunately, due to vaccine hesitancy, some Americans have avoided getting the vaccines they need to best protect themselves from infectious diseases, including from

the most severe consequences of influenza and COVID-19. This has led to unnecessary death, severe illness, and hospitalization." *Id*.

**Defendant's response**: Defendant objects to consideration of the quoted statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

14. As the pandemic progressed, non-governmental epidemiologists have also analyzed data regarding serious adverse events experienced by adults who received the vaccines. "The excess risk of serious adverse events found in [their] study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID19 outcomes. These analyses will require the public release of participant level datasets, which have still not been made available to researchers — but which would allow groups like [theirs] to discern more precisely what the specific risks are for events like myocarditis, heart attacks, strokes, and other potentially serious health consequences." *Assessing America's Vaccine Safety Systems, Part 2: Hearing Before the Select Subcomm. on the Coronavirus Pandemic of the H. Comm. on Oversight and Accountability*, 118th Cong. (Mar. 21, 2024) (statement of Patrick Whelan, Associate Clinical Professor of Pediatrics, UCLA Division of Rheumatology) (available at https://bit.ly/3WCClcl).

**Defendant's response**: Defendant objects to consideration of this PSOF because the information in it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

15. One physician and researcher "had the experience of caring for a young child who suffered a cardiac arrest shortly after receiving his second Covid vaccination. [The physician] filed a VAERS report to bring his plight to the attention of [the physician's] colleagues at the FDA while he was being kept alive in [their] pediatric intensive care unit. A week later, after this young man expired as a result of the anoxic injury to his brain, [the physician] attempted to update the VAERS system to reflect this more tragic outcome — but discovered that the system is not set up to acknowledge a change in outcomes like this." *Id*.

**Defendant's response**: Defendant objects to consideration of this PSOF because the information in it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant. It also contains inadmissible hearsay.

16. The Defendant, U.S. Department of Health and Human Services (HHS), is an agency subject to the Freedom of Information Act (FOIA). 45 C.F.R. § 5.3.

**Defendant's response**: Not Disputed. Defendant objects to this PSOF because it sets forth a legal conclusion, not a statement of material fact.

17. CDC is an "Operating Division" within HHS subject to the agency's FOIA regulations. *See id.*

**Defendant's response**: Not Disputed. Defendant objects to this PSOF because it sets forth a legal conclusion, not a statement of material fact.

18. FDA is an "Operating Division" within HHS subject to the agency's FOIA regulations. *See id.*

**Defendant's response**: Not Disputed. Defendant objects to this PSOF because it sets forth a legal conclusion, not a statement of material fact.

19. At HHS, the "Chief FOIA Officer … has agency-wide responsibility for ensuring efficient and appropriate compliance with the FOIA, monitoring implementation of the FOIA throughout the agency, and making recommendations to the head of the agency to improve the agency's implementation of the FOIA." *Id.*

**Defendant's response**: Defendant objects to this PSOF because it sets forth a legal conclusion, not a statement of material fact. It also is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

20. Under the agency's decentralized FOIA operations, "each FOIA Requester Service Center has a designated official with [the authority of a Freedom of Information At (FOIA) Officer, and] the contact information for each FOIA Requester Service Center is available at http://www.hhs.gov/foia/contacts/index.html." *Id.*

**Defendant's response**: Defendant objects to this statement because it sets forth a legal conclusion, not a statement of material fact. It also is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

21. CDC has a FOIA Requester Service Center. *See* FOIA Contacts, DEP'T OF HEALTH AND HUM. SERVS., http://www.hhs.gov/foia/contacts/index.html.

**Defendant's response**: Defendant objects to this statement because it is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

22. FDA has a FOIA Requester Service Center. *See id*.

**Defendant's response**: Defendant objects to this statement because it is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

23. FDA's Center for Biologics Evaluation and Research does not have its own FOIA Requester Service Center. *See id*.

**Defendant's response**: Defendant objects to this statement because it is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

24. "Freedom of Information Act (FOIA) Officer means an HHS official who has been delegated the authority to release or withhold records; to assess, waive, or reduce fees in response to FOIA requests; and to determine whether to grant expedited processing." 45 C.F.R. § 5.3.

**Defendant's response**: Defendant objects to this statement because it sets forth a legal conclusion, not a statement of material fact. It also is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

25. "In that capacity, the Freedom of Information Act (FOIA) Officer has the authority to task agency organizational components to search for records in response to a FOIA request, and to provide records located in their offices." *Id*.

**Defendant's response**: Defendant objects to this statement because it sets forth a legal conclusion, not a statement of material fact. It also is not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

26. The Plaintiff, John Solomon, is an award-winning investigative journalist, author, and digital media entrepreneur who serves as Chief Executive Officer and Editor in Chief of Just the News, https://justthenews.com. Mr. Solomon has reported for *The Associated Press*, *The Washington Post*, *The Washington Times*, *Newsweek*, *The Daily Beast*, and *The Hill*. Compl. ¶ 4, ECF No. 1.

**Defendant's response**: Defendant does not dispute that Plaintiff in his FOIA request established his role as a member of the media with JusttheNews.com "engaged in the dissemination of information to the public" but objects to the remainder of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing of his FOIA request.

27. On November 10, 2023, the British Medical Journal published an article raising concerns that the "VAERS system isn't operating as intended and that signals are being missed." "[I]n stark contrast to the US government's handling of adverse reaction reports on drugs and devices, the publicly accessible VAERS database on vaccines includes only initial reports, while case updates and corrections are kept on a separate, back end system." The article reported that the FDA division director who oversees VAERS, Narayan Nair, acknowledged that there are "two parts to VAERS, the front-end system and the back end," which contains all updates and corrections—such as a formal diagnosis, recovery, or death. Jennifer Block, *Is the US's Vaccine Adverse Event Reporting System Broken?* 2023 BMJ 383, 2582, https://www.bmj.com/content/383/bmj.p2582.

**Defendant's response**: Defendant objects to consideration of this statement because the information alleged in it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant. Defendant further objects because the quoted statements are hearsay, and as such are inadmissible to establish the truth of the matters asserted.

28. On January 2, 2024, Mr. Solomon submitted separate FOIA requests to CDC and FDA, each seeking "all records of updates and corrections relating to COVID-19 Vaccinations—such as formal diagnoses, recovery, or death—that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database." Compl. Exs. 1 and 3, ECF Nos. 1-1 and 1-3.

**Defendant's Response**: Not disputed.

29. In each request, Mr. Solomon requested "expedited processing … because the matter is one of widespread and exceptional media interest, and I am primarily engaged in the

> dissemination of information to the public. Expedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and uncorrected version and need the requested information to make informal medical decisions." *Id*.

**Defendant's response**: Defendant does not dispute that this quotation appears in each of Plaintiff's FOIA requests but the statements made in this statement set forth Plaintiff's opinions, not fact.

30. On January 3, 2024, CDC denied Mr. Solomon's request for expedited processing because he "failed to show that there is an imminent threat to the life or physical safety of an individual." Compl. Ex. 4 at 9, ECF No. 1-4.

**Defendant's response**: Not disputed.

31. On January 18, 2024, Mr. Solomon, through counsel, filed an appeal with HHS regarding CDC's denial of his request for expedited processing because "CDC failed to consider that [Mr. Solomon] is a 'person primarily engaged in disseminating information' and that there was 'an urgency to inform the public concerning actual or alleged Federal Government activity.'" Compl. Ex. 4 at 2, ECF No. 1-4.

**Defendant's response**: Not disputed but Defendant objects to consideration of this statement because the information was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant to the only issue raised by the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

32. On February 8, 2024, HHS informed Mr. Solomon that his appeal was moot because CDC had previously determined that the request actually "fell under the jurisdiction of [FDA]" and "referred Mr. Solomon's initial request to FDA and administratively closed the initial request." Compl. Ex. 6, ECF No. 1-6.

**Defendant's response**: Not disputed.

33. Since Mr. Solomon filed his FOIA requests, Congress has held multiple hearings addressing America's vaccine safety systems, including the adequacy of the VAERS dataset. *See, e.g.*, Statement of Jernigan, *supra*; Statement of Marks, *supra*; Statement of Whelan, *supra*.

**Defendant's response**: Defendant objects to consideration of this statement because the information in it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It is, accordingly, not material or relevant.

34. Mr. Solomon initiated this action on February 29, 2024. Compl., ECF No. 1.

**Defendant's response**: Not disputed but Defendant objects to consideration of this PSOF because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

35. On April 11, 2024, the Court ordered the parties to file a joint proposed briefing schedule governing further proceedings. *See* Joint Status Report, ECF No. 8.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

36. On May 9, 2024, the parties filed a Joint Status Report, stating the Defendant planned to file a motion to stay under *Open America*, and the Plaintiff planned to oppose the Defendant's motion to stay and file its own cross-motion for partial summary judgment on its request for expedited processing. *Id*.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

37. On May 20, 2024, the parties appeared before the Court for telephonic proceedings, and the Court ordered the parties to appear before the Court again on June 20, 2024 to apprise the Court on how they wish to proceed in this case. See Order, ECF No. 9.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is

not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

38. During the hearing on May 20, 2024, the Court instructed the Defendant to be prepared to apprise the Court of the estimated volume of records potentially responsive to the Plaintiff's request and the nature of the exemptions that would need to be applied to each record by next hearing on June 20, 2024.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

39. On June 18, 2024, the Defendant filed its Motion to Stay, seeking an 18-month stay under *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), and 5 U.S.C. § 552(a)(6)(C), or alternatively under the Court's inherent authority to grant a stay under *Landis v. North American Co.*, 299 U.S. 248 (1936). ECF No. 10.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

40. At the June 20, 2024 hearing, the Defendant was unable to provide the Court any information regarding the estimated volume of records potentially responsive to the Plaintiff's request and the nature of the exemptions that would need to be applied to each record.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

41. In Fiscal Year 2015, CDC received 1,020 requests, had 673 backlogged requests, and spent $2,955,636.00 on processing costs; FDA received 9,958 requests, had 2,337 backlogged requests, and spent $33,911,100.00 on processing costs; and HHS overall received 43,085 requests, 5,745 backlogged requests, and spent $48,575,916.37 on

processing costs. *See* HHS Fiscal Year 2015 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/3ygzT22.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

42. In Fiscal Year 2016, CDC received 1,120 requests, had 374 backlogged requests, and spent $2,237,134.00 on processing costs; FDA received 10,374 requests, had 2,248 backlogged requests, and spent $33,387,345.00 on processing costs; and HHS overall received 34,232 requests, had 4,519 backlogged requests, and spent $48,882,603.08 on processing costs. See HHS Fiscal Year 2016 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/4cVaYzX.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

43. In Fiscal Year 2017, CDC received 1,040 requests, had 87 backlogged requests, and spent $2,534,992.34 on processing costs; FDA received 11,062 requests, had 2,279 backlogged requests, and spent $33,996,472.00 on processing costs; and HHS overall received 34,978 requests, had 4,545 backlogged requests, and spent $52,306,438.13 on processing costs. *See* HHS Fiscal Year 2017 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/3YjC4MY.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

44. In Fiscal Year 2018, CDC received 1,186 requests, had 24 backlogged requests, and spent $2,386,747.41 on processing costs; FDA received 10,256 requests, had 2,666 backlogged requests, and spent $35,000,000.00 on processing costs; and HHS received 35,445 requests, had 6,306 backlogged requests, and spent $49,291,983.16 on processing costs. See HHS Fiscal Year 2018 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/4d02Heq.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

45. In Fiscal Year 2019, CDC received 1,270 requests, had 18 backlogged requests, and spent $2,467,991.00 on processing costs; FDA received 11,578 requests, had 3,172 backlogged requests, and spent $5,000,000.00 on processing costs; and HHS overall received 35,358 requests, had 7,764 backlogged requests, and spent $21,208,131.45 on processing costs. See HHS Fiscal Year 2019 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/3Wco7rY.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

46. In Fiscal Year 2020, CDC received 2,481 requests, had 304 backlogged requests, and spent $2,549,034.00 on processing costs; FDA received 9,951 requests, had 2,825 backlogged requests, and spent $5,000,000.00 on processing costs; and HHS overall received 36,825 requests, had 8,817 backlogged requests, and spent $22,798,827.66 on processing costs. See HHS Fiscal Year 2020 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/46l25gI.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

47. In Fiscal Year 2021, CDC received 2,477 requests, had 282 backlogged requests, and spent $39,696.82 on processing costs; FDA received 8,529 requests, had 3,577 backlogged requests, and spent $5,010,000.00 on processing costs; and HHS overall received 33,158 requests, 9,955 backlogged requests, and spent $23,322,008.15 on processing costs. See HHS Fiscal Year 2021 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/3yiz2hl.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

48. In Fiscal Year 2022, CDC received 2,400 requests, had 257 backlogged requests, and spent $2,924,621.10 on processing costs; FDA received 9,333 requests, had 4,188 backlogged requests, and spent $5,100,000.00 on processing costs; and HHS overall received 38,462 requests, had 11,320 backlogged requests, and spent $29,008,736.17 on processing costs. See HHS Fiscal Year 2022 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/4ddJhlG.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

49. In Fiscal Year 2023, CDC received 1,951 requests, had 186 backlogged requests, and spent $3,840,640.00 on processing costs; FDA received 10,447 requests, had 4,349 backlogged requests, and spent $5,200,000.00 on processing costs; and HHS overall received 46,530 requests, 11,256 backlogged requests, and spent $32,234,029.62 on processing costs. See HHS Fiscal Year 2023 Freedom of Information Annual Report, DEP'T OF HEALTH AND HUM. SERVS., https://bit.ly/4difiJt.

**Defendant's response**: Defendant objects to consideration of this statement because it was not in the record before FDA at the time it denied Plaintiff's request for expedited processing. It also is not material or relevant to the only issue on the parties' cross-motions for summary judgment, *i.e.*, whether Plaintiff is entitled to expedited processing of his FOIA request.

Date: September 20, 2024
Washington, DC

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN SOLOMON,

*Plaintiff,*

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES,

*Defendant*.

Civil Action No. 24-0572 (RBW)

**DECLARATION OF SARAH B. KOTLER**

I, Sarah B. Kotler, declare as follows:

1. I am the Director of the Division of Freedom of Information ("DFOI"), Office of the Executive Secretariat, Office of the Commissioner, Food and Drug Administration ("FDA" or "the agency"), United States Department of Health and Human Services, in Rockville, Maryland.

2. I have held the position of Director of DFOI since January 2015. Prior to becoming Director, I served as Acting Director of DFOI from November through December 2014, after the former Director of DFOI retired. I previously served as DFOI's Deputy Director and Denials & Appeals Officer from September 2013 through October 2014, and as Denials & Appeals Officer from March 2007 through August 2013.

3. As both Deputy Director and Director, I have had supervisory authority over DFOI, which serves as FDA's official point for receiving all requests for records under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. *See* 21 C.F.R. § 20.40. In addition, DFOI is responsible for reporting FDA's FOIA data to the Department of Health and Human Services and the Department of Justice, consulting with other federal agencies regarding FOIA requests, agency-wide FOIA training, and determining whether to grant requests for expedited processing, among

other functions. DFOI also processes requests for FDA's Office of the Commissioner and certain simple requests, such as requests for previously released requests. The majority of FOIA requests (approximately 75 percent) are processed by the FOIA reviewers within FDA's other components.

4. As part of my duties, I assign FOIA requests that relate to the novel coronavirus known as SARS-CoV-2 (also known by the disease it causes, COVID-19) to the appropriate center for processing. Due to the nature of my official duties, I am familiar with the procedures followed by FDA in responding to requests for records pursuant to applicable law, including provisions of the FOIA, 5 U.S.C. § 552. I am also aware of the workload obligations of offices that process FOIA requests across the agency.

5. The statements contained in this declaration are based upon my personal knowledge, upon information I have learned in my official capacity, and upon conclusions I reached based on that knowledge or information.

6. The purpose of this declaration is to provide an overview of FDA's allocation of FOIA resources, including why FDA cannot reallocate resources from other components of the agency to the FOIA office in the Center for Biologics Evaluation and Research ("CBER"). FDA generally cannot reallocate staff from non-FOIA components because performing disclosure reviews is a specialized skill that requires training and expertise. Moreover, reallocating staff carrying out FDA's important public health responsibilities would be contrary to the agency's public health mission. FDA also cannot reallocate staff from non-CBER FOIA components because each disclosure office has its own specialized responsibilities based on the specific types of records that staff are trained to review. In addition, the other FDA FOIA components cannot assist CBER's FOIA office given their own increased workload obligations in recent years. A reallocation of resources from one over-stretched center to another would have an adverse impact

on the agency's ability to meet litigation-imposed processing deadlines and prejudice other important pending requests.

**ALLOCATION OF AGENCY RESOURCES**

7. As detailed in the Declaration of Suzann Burk on June 18, 2024 ("Burk Decl."), ECF No. 10-2, CBER's FOIA resources are currently stretched to their maximum capacity due to marshaling those resources to comply with court-ordered productions in *Pub. Health & Med. Pros. for Transparency* ("*PHMPT*") *v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT I*") and *PHMPT v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT II*"). To meet those production deadlines, and process other requests as it is able, CBER continues to aggressively hire, train, and restructure as it adds new staff. *See* Burk Decl. ¶¶ 24-26, 28-29. But as explained below, FDA cannot reallocate resources to CBER's FOIA office from other important agency functions or components as a means to address CBER's workload.

8. FDA's FOIA program is decentralized because of the agency's size, the large number of records generated during the course of agency business, and the subject-matter expertise required to review highly technical/scientific and specific documents created by different components within FDA. After a FOIA request is received and logged by DFOI, the request is assigned to the FDA component reasonably likely to possess responsive records, which then processes the request. FOIA reviewers within the assigned FDA component process potentially responsive records and then determine whether responsive records should be released in full, redacted in part, or withheld in their entirety under any applicable FOIA exemption or other statutory or regulatory provision.

9. Despite a brief drop at the outset of the COVID-19 pandemic, the number of FOIA requests submitted to FDA has increased in recent years, as has their complexity and the amount

of subsequent FOIA litigation. In fiscal year 2023, FDA received approximately 10,396 new FOIA requests, many of which seek records related to COVID-19. This number of requests represents an increase of 11 percent from the previous fiscal year 2022 (9,333 requests received). By the end of fiscal year 2023, FDA's pending backlog was 4,349 requests (increased from 4,188 at the end of fiscal year 2022). Many recent FOIA requests are more complex and are expected to take longer to process than typical FOIA requests received prior to the beginning of the COVID-19 pandemic. Requests for information related to COVID-19 often require collaboration among federal agencies because they involve records (such as emails) that may have originated in other agencies. Department of Justice guidance advises federal agencies to consult with the originating agency for disclosure determinations. DOJ, *FOIA Update: OIP Guidance: Referral and Consultation Procedures*, https://www.justice.gov/oip/blog/foia-update-oip-guidance-referral-andconsultation-procedures. As a result, FDA regularly collaborates with other federal agencies within the Department of Health and Human Services, such as the Centers for Disease Control and Prevention and the National Institutes of Health, about records responsive to requests. These consultations add both time and complication to the process for responding to FOIA requests.

10. Coupled with the increased number and complexity of requests, FDA has experienced a substantial increase in FOIA litigation in recent years. Between calendar years 2018 and 2020, the number of FOIA lawsuits filed against FDA grew by approximately 200%. In fiscal year 2023, FDA was named as a defendant in 40 new FOIA lawsuits. Currently, FDA is involved in approximately 51 active FOIA litigations, including this one. At the records review and redaction phase, certain FDA components have had to shift some of their FOIA reviewers from responding to FOIA requests in the normal course to almost exclusively processing FOIA requests in litigation. This diversion of staff resources to respond to ever-increasing litigation and

impending court deadlines means that fewer FOIA requests are being processed, and at a slower pace, which may contribute to an increase in litigation.

11. Like CBER, other FDA components' disclosure staff are also over-extended by existing disclosure obligations, many of which concern products or issues similarly important to public health. For example, the following FDA components are processing requests seeking records on, among others: COVID-19 test kits (Center for Devices and Radiological Health); COVID-19 pharmaceutical treatments (Center for Drug Evaluation and Research); infant formula (Center for Food Safety and Applied Nutrition); animal drugs (Center for Veterinary Medicine); electronic nicotine delivery systems, i.e., e-cigarettes and their components (Center for Tobacco Products); inspections of regulated industry (Office of Regulatory Affairs); and agency-wide administrative priorities and responsibilities (Office of the Commissioner).

12. In addition to FOIA, FDA also has numerous other document-processing obligations, including those arising from subpoenas; discovery requests in non-FOIA litigations; oversight requests from Congress; requests from domestic and foreign regulatory bodies; and other statutory disclosure mandates. In some agency offices, the same staff that handles FOIA requests also handles these other disclosure projects because they rely on similar disclosure skills.

13. FDA has taken concrete steps throughout its FOIA offices to reduce backlogs and improve processing time. Specifically, FDA's FOIA offices are recruiting and hiring new employees where funding allows; proactively posting online frequently requested documents to reduce the need for new FOIA requests; training FOIA employees to handle types of records within their component that they do not typically handle, to assist with requests pending in their component's complex track; evaluating requests daily in order to shift them to experienced reviewers as needed; and, where possible, proactively contacting FOIA requesters to negotiate the

scope of requests to produce records more quickly. For example, starting in January 2022, the Center for Drug Evaluation and Research has brought on seven additional employees (six new FDA employees and one employee returning to the center from the Office of Regulatory Affairs) to assist with FOIA processing. Similarly, the Center for Devices and Radiological Health completed a process-improvement review of its FOIA program in October 2019, which included identifying hiring needs; updating workflows, processes, and procedures; training reviewers; and additional tracking of FOIA requests. Between September and December 2019, CDRH acquired a multi-year contract that currently provides 11 contractors to assist in reducing FOIA backlogs and hired additional full-time reviewers to process FOIA requests and other disclosure tasks.

14. However, FDA's resources to hire additional FOIA staff are limited. FOIA is an unfunded mandate—that is, it is not a separate "line item" category in legislative appropriations for the agency and, thus, FOIA operations must be funded from general budgetary appropriations ("Budget Authority"). *See, e.g.*, DOJ, *FOIA Update: FOIA Affected by Budget Constraints*, https://www.justice.gov/oip/blog/foia-update-foia-affected-budget-constraints. Budget Authority funds are necessary to cover critical needs across the entire agency—for fiscal year 2024, for example, the agency's Budget Authority estimations cover activities ranging from ensuring that the human food supply is safe (including the modernization of the country's infant formula supply chain), to curbing the unlawful marketing of tobacco products targeted at youth, to mitigating the harms associated with the prescription opioid epidemic. *See* FDA, *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, https://www.fda.gov/media/1661

82/download?attachment (last accessed October 30, 2023). Accordingly, when FDA receives more FOIA requests, there is no specific FOIA funding available for hiring more employees.

15. Despite the limitations on FDA's resources for FOIA funding, the agency has made extraordinary efforts to maximize efficiencies and hire and train new employees to assist CBER's FOIA office in reducing its backlog and meet court-ordered productions. *See* Burk Decl. ¶¶ 24-25, 28-29. These efforts, along with the agency's request for a stay of cases like this one, represent CBER's best chance of complying with its voluminous court orders and reducing its FOIA backlog, while ensuring that sensitive information remains protected through a careful, line-by-line review of records to be released publicly. The reallocation of staff from non-FOIA components or non-CBER components, on the other hand, are not viable solutions to CBER's unprecedented situation.

16. FDA generally cannot reallocate staff from non-FOIA components, with very rare exceptions for short-term details. Importantly, it would be contrary to FDA's public health mission to pull staff away from, for example, reviewing cancer treatment applications or conducting counterfeit medication investigations to have them perform work for which they are untrained and unqualified. Moreover, performing disclosure reviews is a specialized skill that requires training and expertise that the vast majority of FDA staff does not have. It is not reasonable to expect that a microbiologist who performs laboratory assays, a pharmacist who reviews drug applications, a badging office employee who issues credentials, or a mail room clerk who organizes mail can simply begin performing disclosure review without significant training. And any offices from which these resources were commandeered would face their own shortfall.

17. More specifically, it would not be feasible to reallocate staff from non-CBER disclosure offices for two reasons. First, those other offices do not have resources to spare.

Assigning disclosure staff from outside CBER to review CBER records would compromise the other offices' ability to keep up with their own disclosure review responsibilities. Second, such re-assignment would be extremely inefficient because disclosure matters are different in the agency's disclosure offices. Each FDA component's disclosure office has its own specialized responsibilities and expertise to ensure consistency and efficiency in reviewing the types of records handled by that office for public release. Although all disclosure staff will be familiar with FOIA's requirements and FDA's general disclosure regulations in 21 C.F.R. Part 20, most centers, including CBER, have their own disclosure regulations outside of 21 C.F.R. Part 20, and staff from each center are trained to review information regularly maintained by their center. For example, CBER FOIA reviewers are familiar with the types of information regularly contained in biologics license applications and are trained to identify information that is exempted from disclosure in those files; CBER FOIA reviewers would not be expected to be familiar with records commonly processed by other parts of the agency, such as premarket tobacco product applications or food additive petitions. The converse is also true; reviewers in FDA's Center for Food Safety and Applied Nutrition are familiar with records regularly maintained by that center but would not have the same expertise as a CBER reviewer when looking at a biologics license application. Thus, disclosure staff in different FDA centers are not interchangeable.

18. Even when the agency can allocate new monetary resources to hire new disclosure staff or contractors, it takes substantial time to recruit and hire new staff, bring them on board, and provide them with the necessary training to become competent to perform disclosure reviews. FDA estimates that it takes approximately two years to fully train a new disclosure reviewer. In the meantime, experienced reviewers are needed to closely supervise and review their work – thus decreasing the amount of time that experienced reviewers can spend reviewing records. Indeed, as

explained in the Burk Declaration (¶ 30), CBER staff continue to expend significant time on supervision and review of newly hired employees. As a result, it is not reasonable to expect that FDA will be able to respond to CBER FOIA requests more quickly by allocating non-disclosure or non-CBER resources.

**CONCLUSION**

19. In sum, FDA is committed to transparency in all aspects of its work, especially its response to the COVID-19 pandemic. But given the limited number of FDA staff available to perform disclosure reviews and the heavy workload FDA's disclosure offices are facing, it would be unduly burdensome for FDA to reallocate resources from agency components outside of CBER. If required to do so, FDA's ability to perform its other agency functions, including responding to other record requests, would likely be impaired.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on September 20, 2024.

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2024.09.20 08:46:15 -04'00'

SARAH B. KOTLER
Director of Division of Freedom of Information
Office of the Executive Secretariat
Food and Drug Administration
U.S. Department of Health and Human Services

# DEFENDANT'S EXHIBIT 1

Gmail

Michael Ding <michael.ding@aflegal.org>

## FOIA Request - Time sensitive

1 message

**John Solomon** [redacted] Tue, Jan 2, 2024 at 11:40 AM
To: FDAFOIA@fda.hhs.gov
Cc: John Solomon [redacted]
Bcc: michael.ding@aflegal.org

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
via email: FDAFOIA@fda.hhs.gov

Dear FDA FOIA Office:

I request, under the Freedom of Information Act, all records of updates and corrections relating to COVID-19 Vaccinations —such as formal diagnoses, recovery, or death—that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database.

This is not intended to be a complex request, so I am happy to work with you to refine it if you are unsure what records would be responsive. I have included my cell phone below for convenience

The data we are specifically seeking was discussed publicly by the FDA official Narayan Nair, as quoted by the British Medical Journal in an article published in November 2023. She described the data as belonging in a "back end" system accessible to CDC and FDA officials and not in the publicly available VAERS database.

This data has enormous value to the public's understanding of vaccine safety and efficacy and how the government surveils for safety signas.

The data records constitute public records as defined by law since they were gathered by government agencies as part of their official duties. And the data can be released in anonymized form to protect any medical privacy concerns of individual Americans.

I request a media fee waiver as a journalist with JusttheNews.com, which delivers old-fashioned, honest, and exclusive reporting in a neutral voice but through the modern channels of Rumble, podcasts, e-books, and social media. I make this request in the public interest for the purpose of distilling and disseminating information.

I also request expedited processing of this request because the matter is one of widespread and exceptional media interest, and I am primarily engaged in the dissemination of information to the public. Expedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and uncorrected version and need the requested information to make informed medical decisions.

I would like to receive the records digitally by email. If it would expedite the processing of records, I consent to the release of responsive records on a rolling basis.

Thank you,

John Solomon
Editor in Chief
Just the News
[redacted]

# DEFENDANT'S EXHIBIT 2

Gmail

Michael Ding <michael.ding@aflegal.org>

## FOIA Request - Time Sensitive

1 message

**John Solomon** [redacted]
Cc: John Solomon [redacted]
Bcc: michael.ding@aflegal.org

Tue, Jan 2, 2024 at 11:50 AM

Roger Andoh, FOIA Officer
MS-D54
1600 Clifton Road, N.E.
Atlanta, GA 30333
via email: FOIARequests@cdc.gov]

Dear Roger and CDC FOIA Office:

I request, under the Freedom of Information Act, all records of updates and corrections relating to COVID-19 Vaccinations —such as formal diagnoses, recovery, or death—that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database.

This is not intended to be a complex request, so I am happy to work with you to refine it if you are unsure what records would be responsive. I have included my cell phone below for convenience

The data we are specifically seeking was discussed publicly by the FDA official Narayan Nair, as quoted by the British Medical Journal in an article published in November 2023. She described the data as belonging in a "back end" system accessible to CDC and FDA officials and not in the publicly available VAERS database.

This data has enormous value to the public's understanding of vaccine safety and efficacy and how the government surveils for safety signals.

The data records constitute public records as defined by law since they were gathered by government agencies as part of their official duties. And the data can be released in anonymized form to protect any medical privacy concerns of individual Americans.

I request a media fee waiver as a journalist with JusttheNews.com, which delivers old-fashioned, honest, and exclusive reporting in a neutral voice but through the modern channels of Rumble, podcasts, e-books, and social media. I make this request in the public interest for the purpose of distilling and disseminating information.

I also request expedited processing of this request because the matter is one of widespread and exceptional media interest, and I am primarily engaged in the dissemination of information to the public. Expedited processing is critical because patients, doctors, and other public users of the VAERS database may have access only to an incomplete and uncorrected version and need the requested information to make informed medical decisions.

I would like to receive the records digitally by email. If it would expedite the processing of records, I consent to the release of responsive records on a rolling basis.

Thank you,

John Solomon
Editor in Chief
Just the News
[redacted]

# DEFENDANT'S EXHIBIT 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

January 3, 2024

Mr. John Solomon
Editor in Chief
Just the News
[redacted]
Via email: [redacted]

Dear Mr. Solomon:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated January 2, 2024 (request attached). Your request assigned number is 24-00444-FOIA, and it has been placed in our complex processing queue.

**Extension of Time**
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:

- We reasonably expect to consult with two or more Centers/Institutes/Offices, and
- We reasonably expect to consult with other federal Agencies.

If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, please contact the analyst handling your request Zachary Roberts at ltk2@cdc.gov or our FOIA Public Liaison, Bruno Viana at 770-488-6246. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

**Expedited Processing**
You requested that we expedite processing your request. Your request is denied because:

- You have failed to show that there is an imminent threat to the life or physical safety of an individual.

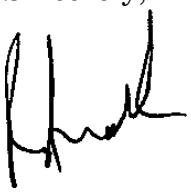
**Fee Category**
Because you are considered a "News Media requester," you will not be charged fees unless you choose to receive responsive records in hard copy. (10 cents/page)
**Appeal Rights**

You have the right to appeal the agency's expedited processing response to your request. You may file your appeal with the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by April 2, 2024.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact Zachary Roberts at ltk2@cdc.gov.

We reasonably anticipate that you should receive documents by March 25, 2024. Please know that this date roughly estimates how long it will take the Agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

24-00444-FOIA

# DEFENDANT'S EXHIBIT 4

U.S. FOOD & DRUG ADMINISTRATION

January 03, 2024

JUST THE NEWS
JOHN SOLOMON
[redacted] US

In Reply refer to
FOIA Control #:
2024-54

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

I request, under the Freedom of Information Act, all records of updates and corrections relating to COVID-19 Vaccinations—such as formal diagnoses, recovery, or death—that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database. The data we are specifically seeking was discussed publicly by the FDA official Narayan Nair, as quoted by the British Medical Journal in an article published in November 2023. She described the data as belonging in a "back end" system accessible to CDC and FDA officials and not in the publicly available VAERS database.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm. PLEASE NOTE: HOURLY RATES FOR SEARCH AND REVIEW INCREASED FOR ALL REQUESTS RECEIVED ON OR AFTER JUNE 1, 2023.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Wilson M. Russ, Freedom Of Information Specialist, at (301) 796-8981 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

# DEFENDANT'S EXHIBIT 5

U.S. FOOD & DRUG ADMINISTRATION

January 08, 2024

JUST THE NEWS
JOHN SOLOMON
7868 Elsinore Drive
Manassas VA 20112 US

In Reply refer to
FOIA Control #:
2024-54

Requester reference:

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

I request, under the Freedom of Information Act, all records of updates and corrections relating to COVID-19 Vaccinations—such as formal diagnoses, recovery, or death—that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database. The data we are specifically seeking was discussed publicly by the FDA official Narayan Nair, as quoted by the British Medical Journal in an article published in November 2023. She described the data as belonging in a "back end" system accessible to CDC and FDA officials and not in the publicly available VAERS database.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director

# DEFENDANT'S EXHIBIT 6

AMERICA FIRST LEGAL

January 18, 2024

**Via online portal:** https://requests.publiclink.hhs.gov/App/Index.aspx
**Via email:** William.Holzerland@hhs.gov

William Holzerland
U.S. Department of Health and Human Services
Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue SW
Washington, DC 20201

**FOIA Appeal: Denial of Expedited Processing for Request 24-00444-FOIA**

Dear Mr. Holzerland:

I am representing John Solomon, Editor in Chief of Just the News relating to his January 2, 2024, Freedom of Information Act (FOIA) request to the Centers for Disease Control (CDC) for all records of updates and corrections relating to COVID-19 Vaccinations that are collected after the initial reports to the Vaccine Adverse Event Reporting System (VAERS), but that are not published in the public VAERS database, i.e. the "back end" system described by FDA official Narayan Nair, as quoted by the British Medical Journal in an article published in November 2023. Exhibit 1.

On January 3, 2024, the CDC stated that Mr. Solomon "failed to show that there is an imminent threat to the life or physical safety of an individual" and denied his request for expedited processing. Exhibit 2.

Because Mr. Solomon's request fulfills the statutory and regulatory requirements for expedited processing, he now appeals the CDC's erroneous determination.

## I. Standard of Review

The FOIA mandates expedited processing when a requestor demonstrates a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). "Compelling need," is established when "a failure to obtain requested records on an expedited basis … could reasonably

Washington, DC 20003 Monroe, Georgia 30655

www.aflegal.org



be expected to pose an imminent threat to the life or physical safety of an individual; or," when the request is "made by a person primarily engaged in disseminating information," there is "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(I)–(II). The Department's regulations for evaluating requests for expedited processing mirror the FOIA statute. *See* 45 C.F.R. § 5.27(b).

## II. Argument

Because Mr. Solomon is "a person primarily engaged in disseminating information," the "compelling need" for expedited processing may be established by an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. §§ 552(a)(6)(E)(i)(I), (v)(II); 45 C.F.R. § 5.27(b)(2). The CDC denied expedited processing solely on the grounds that Mr. Solomon "failed to show that there is an imminent threat to the life or physical safety of an individual." Exhibit 2. This is not the standard. The CDC failed to consider that Mr. Solmon is a "person primarily engaged in disseminating information" and that there was an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II); 45 C.F.R. § 5.27(b)(2). Because Mr. Solmon's request met these conditions, expedited processing must be granted.

First, Mr. Solmon is "a person primarily engaged in disseminating information." 5 U.S.C. § 552(a)(6)(E)(v)(II). As he described in his request, he is a journalist for JusttheNews.com, and he made this request in the public interest for the purpose of distilling and disseminating information. The CDC acknowledged this when it granted his request for a fee waiver. *See* Exhibit 2.

Second, there is "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). FDA official Narayan Nair acknowledged that the requested records concern actual Federal Government activity. *See* Jennifer Block, *Is the US's Vaccine Adverse Event Reporting System Broken?*, 2023 BMJ 383, 2582 (available at http://tinyurl.com/3tppes4t). The requested information is critical to the public's understanding of vaccine safety and efficacy. The request is "urgent" because—without access to the requested information—individuals decide everyday whether to take the COVID-19 Vaccine or additional booster shots with incomplete information about what dangers they unknowingly assume.

For example, the public VAERS database reportedly did not include an autopsy examiner's conclusion that the death of a 15-year-old boy was caused by "stress cardiomyopathy following [his] second dose of the Pfizer-BioNTech covid-19 vaccine." *Id.* Accordingly, there is a compelling need for the CDC to disclose the requested information on an expedited basis. Undisclosed risks presented by the vaccines, including the recent discovery of billions of DNA fragments per dose of the Pfizer and

Moderna vaccines, have caused the Florida Surgeon General to call for the halt of their use until more information is disclosed. *Press Release: Florida State Surgeon General Calls for Halt in the Use of COVID-10 mRNA Vaccines*, FLA. DEP'T OF HEALTH (Jan. 3, 2024), http://tinyurl.com/yc7w6ucp. Even if the standard applied by the CDC were the only standard, the urgency to expose the requested information is such that there *is* an imminent threat to the life or physical safety of the general public.

## III. Conclusion

Accordingly, I request that the CDC's determination be reversed and Mr. Solomon's request for expedited processing be granted. Please contact me at michael.ding@aflegal.org for additional clarification or information.

Sincerely,

/s/ Michael Ding
America First Legal

Foundation CC: John Solomon, Editor in Chief, Just the News

# DEFENDANT'S EXHIBIT 7

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

**Case No. 2024-00087-A-PHS**

**February 8, 2024**

Michael Ding
America First Legal Foundation
611 Pennsylvania Ave SE #231
Washington, DC 20003
Via email: michael.ding@aflegal.org

Dear Mr. Ding:

On January 2, 2024, Mr. John Solomon, Editor in Chief of Just the News, submitted a Freedom of Information Act (FOIA) request to the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR). The CDC/ATSDR FOIA Office assigned the initial request tracking number 24-00444-FOIA. Mr. Solomon asked the agency for expedited processing, but his request was denied.

On Mr. Solomon's behalf, you submitted an administrative appeal of the agency's denial of expedited processing on January 18, 2024. This office (OS FOIA) assigned your appeal tracking number 2024-00087-A-PHS.

On January 17, 2024, however, the CDC/ATSDR FOIA Office determined that Mr. Solomon's initial request fell under the jurisdiction of the Food and Drug Administration (FDA). On January 22, 2024, the CDC/ATSDR FOIA Office informed OS FOIA that the agency had referred Mr. Solomon's initial request to FDA and administratively closed the initial request.

**CONCLUSION:**

Because the initial request underlying your appeal has been administratively closed and referred to FDA, Mr. Solomon's request for expedited processing by CDC/ATSDR is moot. Accordingly, your appeal is also moot, and it is hereby administratively closed.

Alesia Y. Williams -S
Digitally signed by Alesia Y. Williams -S
Date: 2024.02.08 08:15:14 -05'00'

Alesia Y. Williams
Director, FOIA Appeals and Litigation
FOI/Privacy Acts Division

Copy to:
CDC/ATSDR FOIA Officer

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN SOLOMON,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 24-0572 (RBW)

**[PROPOSED] ORDER**

UPON CONSIDERATION of Plaintiff's Motion for Partial Summary Judgment and Defendant's Cross-Motion for Partial Summary Judgment on Its Denial of Plaintiff's Request for Expedited Processing, the oppositions thereto, and entire record herein, it is hereby:

ORDERED that Plaintiff's motion is DENIED and Defendant's Cross-Motion is GRANTED.

SO ORDERED:

Date

REGGIE B. WALTON
United States District Judge