UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civ. A. No. 23-220 (RDM)

PLAINTIFF'S MOTION FOR ORDER FOR TIMELY PROCESSING

Plaintiff Children's Health Defense (CHD) respectfully moves the Court to order timely processing of its July 2022 FOIA request for records of Defendant Food and Drug Administration's (FDA) post-authorization safety-monitoring of COVID-19 vaccines. Specifically, CHD asks the Court to order FDA to (1) within 30 days, produce the150 responsive EB data-mining records that were located by the Agency over a year and a half ago; (2) immediately begin processing of the remainder of CHD's request; and (3) within 30 days, provide a status report and proposed production schedule for all remaining responsive documents.

CHD makes this motion pursuant to the Freedom of Information Act, 5 U.S.C. § 552, and this Court's Minute Order of October 24, 2024. The accompanying Memorandum of Points and Authorities sets for the basis for this Motion.

Respectfully submitted this 21st day of November 2024, by

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PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR ORDER FOR TIMELY PROCESSING

Introduction

The contrast between the Food and Drug Administration's purported commitment to transparency and its ongoing refusal to disclose safety-monitoring data for COVID-19 vaccines has become as ironic as it is stark. In comments made this month, Dr. Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research, lamented rising vaccine "hesitancy," and emphasized that the best way for the FDA to combat it is to be *transparent*.[1] Marks observed: "I think one thing we have learned about vaccination: If we're honest about this, *if we're transparent*, hopefully people will understand the benefits-risk [calculations] here and feel confident in their use. . ." *Id*. (emphasis added). Meanwhile, in the District of Columbia alone,

[1] *See Q&A with the FDA's top vaccine regulator amid a fresh wave of disinformation,* by Helen Branswell, STAT, Nov. 4, 2024, at https://www.statnews.com/2024/11/04/fda-vaccine-regulation-peter-marks-fight-disinformation-with-transparency/ (*Q&A*).

the FDA has since 2023 sought and obtained stays in at least five FOIA lawsuits that seek records of the Agency's COVID-19 vaccine safety monitoring (including the instant lawsuit).[2]

If vaccine hesitancy is on the rise, especially in connection with COVID-19 vaccines, it is no wonder. On the one hand, the FDA and CDC continue to tout vaccine safety, and the FDA recently approved yet another round of COVID-19 booster shots.[3] On the other hand, new evidence of harm from the vaccines continues to mount. For example, a November 17, 2024, peer-reviewed autopsy study found a "high likelihood of a causal link between COVID-19 vaccines and death."[4] Another November 2024 peer-reviewed study analyzed VAERS data and found COVID-19 vaccines pose a 112,000% greater risk of brain clots and strokes than flu vaccines and a 20,700% greater risk of those symptoms than all other vaccines combined.[5]

Consistent with previous remarks,[6] in his comments this month, Dr. Marks highlighted the FDA's own monitoring of VAERS as evidence that the federal government is working

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[2] In addition to the stay order in the instant case, *see CHD v. FDA*, No. 23-cv-02316-TJK, (D.D.C.) Minute Order dated 12/13/23; *CHD v. CDC*, No. 23-cv-00431-TNM (D.D.C.), ECF 28, Memorandum Order; *ICAN v. FDA*, No. 23-cv-219-RBW (D.D.C.), ECF 27, Stay Order; *Wright v. HHS*, No. 22-cv-1378-RC (D.D.C.), ECF 28, Stay Order.

[3] See *FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants*, at https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently (last accessed Nov. 20, 2024) (FDA notes "[t]hese updated vaccines meet the agency's rigorous, scientific standards for safety" and "strongly" encourages all those eligible to receive the updated vaccine); *see also Staying Up to Date with COVID-19 Vaccines*, at https://www.cdc.gov/covid/vaccines/stay-up-to-date.html (last accessed Nov. 20, 2024) (CDC urges everyone 6 months and older to get 2024-2025 vaccine).

[4] *A Systematic Review of Autopsy Findings In Deaths After COVID-19*, Nicholas Hulscher, et al, Science, Public Health Policy and the Law, 11/17/24, at https://publichealthpolicyjournal.com/a-systematic-review-of-autopsy-findings-in-deaths-after-covid-19-vaccination/

[5] *COVID-19 Vaccines: A Risk Factor for Cerebral Thrombotic Syndromes*, Rogers, C., et al, International Journal of Innovative Research in Medical Science, Vol. 09, Iss. 11, at Table 3, November 2024, https://ijirms.in/index.php/ijirms/article/view/1982/1420.

[6] *See* February 2024 testimony of Dr. Marks before the Select Subcommittee on the Coronavirus Pandemic Committee On Oversight and Accountability, U.S. House of Representatives https://oversight.house.gov/wp-content/uploads/2024/02/FDA-SSCP-Vaccine-Safety-and-

diligently to ensure vaccine safety, noting that the FDA monitors VAERS to determine whether adverse events reported after vaccination, are "truly related or not."[7] Unfortunately, however, if the FDA continues to have its way, transparency about the Agency's safety-monitoring of COVID-19 vaccines will not be coming any time soon.

Contrary to Dr. Marks' exhortations, the FDA says that the VAERS monitoring records it located over a year and a half ago—Empirical Bayesian data mining records that speak directly to the question of whether reported adverse events and COVID-19 shots are "truly related or not"—are too "sensitive" to disclose without months of consultations among attorneys from at least three different federal agencies. *See* ECF 34, JSR, ¶¶ 1-3. Meanwhile, the remainder of CHD's request for VAERS-monitoring records continues to languish in a processing queue that the FDA has understaffed for years, and as this Court has recognized, under the FDA's timeline, by the time these records are provided to CHD, they will be stale and valueless. So much for transparency!

Although this Court's October 24, 2024, Minute Order defers to the Agency's proposed processing timeline, such deference is neither required nor appropriate under the current circumstances. Indeed, this Court's hands are not tied by the mere fact that CHD's request is languishing behind other requests in an understaffed processing queue. Especially now that the six- month *Open America* stay has expired, the Freedom of Information Act empowers and obligates the Court to ensure timely processing, where CHD requested the records on an expedited basis over two years ago; where new information indicates that the urgent need for the requested safety-monitoring records continues to grow and the harms from the FDA's failure to

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Surveillance-FDA-Written-Testimony-FINAL-Clean.pdf (February 15, 2024), pp. 1, 3, 4 (discussing COVID-19 vaccine safety-monitoring).

[7] *See Q&A, supra*, note 1.

disclose continue to multiply; and where, as this Court has acknowledged, the FDA's extended processing timeline virtually guarantees that the records will be stale and worthless by the time they are finally produced.

Background

CHD Requests Expedited Processing of Request for Safety-Monitoring Records:

Over two years ago, on July 27, 2022, CHD submitted a FOIA request to FDA, seeking on an expedited basis records of the Agency's monitoring of VAERS to determine whether any of the adverse events reported after COVID-19 vaccination were caused by the shots. ECF 1, Complaint, ¶16. Among other things, the request sought records of the Empirical Bayesian data mining ("EB mining") conducted by the Agency to look for statistical indications that an adverse event could have been caused by the shot, as well as communications regarding any "safety signals" that were detected through the EB mining. *Id*. The public significance of the EB mining records is evidenced by the fact that since 2022, at least three other requestors have tried to obtain them from the FDA—without success.[8]

CHD's July 2022 FOIA request included detailed, fully-cited arguments as to why expedited processing was appropriate, discussing, among other things, the federal government's relentless promotion of COVID-19 vaccines despite widespread concerns about the safety of the shots, and the public's need to make fully informed medical decisions. ECF 1-1, Exhibits, pp. 7-10. CHD argued that the standard for expedited processing was met because CHD disseminates information to the public, and the public has an urgent need to fully understand how the FDA has followed through on its promise to vigilantly monitor COVID-19 vaccine safety; what safety

[8] The requestors include the Epoch Times, the Informed Consent Action Network, and Sen. Ron Johnson.

signals the Agency has discovered; how it has investigated any safety signals it has detected through the EB mining; and why the Agency continues to conclude the shots are safe. *Id*. CHD noted that a lack of transparency both deprives people of information needed to make fully informed medical and political decisions, and erodes confidence in federal public health guidance. *Id*.

CHD Sues after FDA Denies Expedited Processing and Denies Request:

Although the FDA did not dispute that CHD disseminates information to the public, it denied expedited processing in a boiler-plate letter stating that the standard for "urgency" was not met. ECF 1-1, Exhibits, p. 16. Despite this denial, however, the Agency moved quickly to dispose of the request: on October 4, 2022, rather than searching for and reviewing records as required by the FOIA and HHS's FOIA-processing regulations, the Agency issued a determination letter denying CHD's FOIA request in *total*, claiming the requested safety-monitoring records were exempt from disclosure under FOIA Exemption (b)(5). ECF 1, Complaint, ECF 1-1, ¶¶ 22-28; Exhibits, pp. 20-21.

CHD filed an immediate administrative appeal, asking the Agency to search for and produce responsive records, as required by the FOIA and HHS regulations. ECF 1, Complaint, ¶ 29. After FDA indicated the administrative appeal process would take about 9-12 months, far exceeding FOIA time limits (*id*. ¶ 31), CHD sued FDA on January 26, 2023. *See id.* In the complaint, CHD asked the court to provide expeditious proceedings in the action and to order the FDA to search for and produce all non-exempt records within 20 days of its ruling. *Id*. p. 12.

FDA Locates EB Data-Mining Records and Obtains a Six-Month Stay:

In the spring of 2023, in the context of a FOIA lawsuit brought by a different plaintiff, FDA located 150 EB data mining records that are directly responsive to CHD's FOIA request. *See* ECF 19, Plaintiff's Opposition to a Stay, pp. 23-5; ECF 20, Defendant's Reply, pp. 15-16. However, the FDA refused to produce those documents. Instead, on September 14, 2023, FDA filed a Motion for an Eighteen-Month Stay of Proceedings under *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), due to the production obligations imposed on the Agency by a Texas court in FOIA litigation involving COVID-19 vaccine licensing records. *See* ECF 17, Motion to Stay.

On January 12, 2024, this Court issued a six-month stay under *Open America*. ECF 25. The Court ordered the parties to file a joint status report (JSR) by June 14, 2024, notifying the Court as to whether a further stay was appropriate. *Id*.

The Non-Exempt Nature of the EB Data-Mining Records:

The undisclosed EB data-mining records appear to consist of 75 Excel spreadsheets, each containing records of the FDA's regularly-conducted statistical analysis of VAERS using EB mining, with each spreadsheet accompanied by a cover email. *See* ECF 22, Plaintiff's Sur-Reply in Opposition to Stay, p. 7. As for the contents of the spreadsheets, the instant lawsuit involves a second FOIA request, which sought the EB mining records used in a 2022 article by FDA scientists who concluded that reporting rates for death following COVID-19 vaccination were lower than expected. *See* ECF 1, Complaint, ¶ 14; ECF 1-1, Exhibits, p. 4.[9] In response to that second FOIA request, the FDA has produced a one-page pdf of an EB mining record, converted

[9] The article is *Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021* (B. Day et al.), here: https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.

from an Excel spreadsheet. *See* ECF 15, JSR, ¶¶ 3, 5. The EB-mining record contains no redactions, and appears as follows:

Vaccine Name	Symptom: PT	HLT	HLGT	SOC	N	EBGM	EB05	EB95	PRR	RR	E
COVID19 (COVID19 (JANSSEN))	Vaccination failure	Therapeutic and nontherapeutic responses	Therapeutic and nontherapeutic effects (excl toxicity)	Genrl	51	3.164	2.518	3.935		3.654	13.956

On information and belief, the column abbreviations refer to the following:[10]

- HLT= High Level Term
- HLGT=High Level Group Term
- SOC=Primary System Organ Class
- N=Number of individuals with symptom
- EBGM=Empirical Bayesian Geometric Mean
- EB05=Error bar
- EB 95=Error bar
- PRR=Proportional Reporting Ratio
- RR=Relative Reporting
- E=Expected number of individuals with system

Although FDA characterizes the remaining, undisclosed 75 EB-mining records as containing potentially "sensitive" data (see ECF 34, Status Report of Oct. 18, 2024, ¶ 3), the Agency has not indicated that the records are likely to fall under any particular FOIA exemption. Presumably, the undisclosed files contain the same or similar columns of non-exempt, non-redactable data as the file reproduced above.

FDA Seeks Renewed Stay, while CHD Seeks Processing Order:

When the six-month *Open America* stay expired in June 2024, the parties filed the court-ordered JSR to address whether a further stay was appropriate. *See* ECF 28, June 14 JSR. The

[10] *See Submitting Study Datasets for Vaccines to the Offices of Vaccines Research and Review: Guidance for Industry*, at https://www.fda.gov/media/112581/download (last accessed November 19, 2024).

FDA asked the Court to continue the stay. *Id*. at ¶ 23. CHD objected and asked the Court to issue a production and processing order, arguing that *Open America* precluded a renewed stay because (1) new information from the FDA demonstrated that while the FDA might be working diligently to process records for the Texas litigation, the Agency has not exercised due diligence in processing any non-Texas requests in the complex track, including CHD's; and (2) the need for the vaccine safety-monitoring records continued to be urgent, especially in light of growing recognition of COVID-19 vaccine injuries coupled with ongoing claims by FDA officials that the Agency's safety monitoring shows the vaccines are safe. *Id*., ¶¶ 1-17.

On July 9, 2024, the Court held a status conference. *See* ECF 30, Transcript of July 9 Status Conference. The Court stated, "I am inclined to at least get the process going here and not to simply say, we need to wait another year or two years or three years before the process even begins." *Id.*, p. 3, lines 2-4. The Court asked FDA counsel various questions relating to "due diligence" and "urgency" (*id*. pp. 3-8), and in a July 11, 2024, Minute Order, directed FDA to answer some of those questions, with an opportunity for CHD to respond. *See* Minute Order of July 11, 2024.

Notably, during the July 9, 2024, status conference, FDA did not argue that it is incapable of processing CHD's request; to the contrary, FDA's counsel assured this Court that if processing is ordered, "the FDA will do everything in its power to comply with this Court's order." *See* ECF 30, Transcript of July 9 Status Conference *Id*. p. 5, lines 20-21.

On August 9, 2024, FDA responded to the Court's questions relating to urgency and diligence, and reiterated its request for a further stay. ECF 31, Defendant's Status Report. FDA indicated that none of the safety-monitoring records sought by CHD have yet been released to the public. See ECF 31, Defendant's Status Report, ¶¶ 1-7; ECF 32, Plaintiff's Response, pp. 2-

3. FDA estimated that to complete processing of the responsive EB-mining records would take one full month of FOIA staff time, and that in the absence of a court order, the Agency would not begin processing the EB mining records or the remainder of CHD's FOIA request for approximately 24 to 36 months. ECF 31, Defendant's Report, ¶¶ 8, 27-34. In its response, CHD argued that FDA's status report confirmed both the Agency's lack of diligence in responding to CHD's request, and the urgent need for the records; accordingly, CHD again requested that the Court deny a renewed stay and issue a production and processing order. ECF 32, Response to Status Report, August 16, 2024, pp. 2-8.

On October 4, 2024, the Court held a second status conference. The Court stated that it agreed "completely" with CHD's observation that waiting another two to three years to disclose the records would render the records stale and of no value. ECF 33, Transcript of Oct. 4 Status Conference, p. 8, lines 8-12. The Court stated, "I am open to the notion of saying, just produce it and do it," but expressed concern that "when I am doing that. . .someone else is not going to get their records who is ahead of you in the queue. That is what troubles me is why. . .given the limited resources and the unreasonable demands from the Texas litigation, why do you get to jump the queue over the person whose records would otherwise be processed right now?" I*d.*, lines 16-23.

On October 7, 2024, the Court ordered the parties to file another status report. In this report, FDA acknowledged that the time required for FOIA staff to finish processing of the 150 responsive EB mining records is "not expected to be great," but the Agency nonetheless requires a minimum of "several additional months" for attorneys from various agencies to resolve "releasability questions" surrounding the records, because the records "concern potentially sensitive data." *See* ECF 34, Status Report of Oct. 18, 2024, ¶¶ 1-3. CHD reiterated its previous

requests that the Court deny FDA's request for a renewed stay, and order immediate processing and production. *Id*. ¶ 22.

Court Orders Processing Starting in August 2026, with Possibility of Earlier Start Date:

Following the briefing and status conferences described above, the Court did not renew or extend the six-month *Open America* stay that expired in June 2024. Instead, the Court ordered FDA to "begin processing the responsive documents no later than August 9, 2026, and, to the extent possible and consistent with the placement of the request in the queue of similarly situated requesters, at an earlier date." *See* Minute Order of October 24, 2024. As a basis for this extended processing timeline, the Court noted that in the August 9 status report, "Defendant represented that the 'agency's best estimate of when it will begin processing Plaintiff's FOIA request' is 'when it reaches the front of the Complex Track in approximately 24 to 36 months.'" *Id*. The Court also noted that other requesters filed their requests before CHD's, and it would be "unfair to push those requests further back in the queue." *Id*.

The processing order was without prejudice to CHD to seek an earlier processing date based on changed circumstances or new information. *Id*.

Argument

It is beyond dispute that "[t]imely disclosure of records is . . . essential to the core purpose of FOIA,"[11] and "stale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). Since "[e]xcessive delay by [an] agency in its response is often tantamount to denial," *Open America*, 547 F. 2d 605, 617 (D.C. Cir. 1976) (Leventhal, J., concurring), the FOIA sets forth a detailed timeline for an agency's processing of

[11] *Memorandum for Heads of Executive Departments and Agencies re Freedom of Information Act Guidelines*, OFFICE OF THE ATTORNEY GENERAL, WASHINGTON D.C. (Mar. 15, 2022), p. 3, at https://www.justice.gov/media/1212566/dl?inline.

FOIA requests. *See, e.g.*, 5 U.S.C. § 552(a)(6)(A)(i) and § 552(a)(6)(C)(i)) (upon receipt of request, agency must, within 20 days, notify the requestor whether it will comply, and after deciding to comply, must make responsive records "promptly available" to the requestor); § 552(a)(6)(A)(ii) (agency must rule on administrative appeals within 20 business days); § 552(a)(6)(E) (agency must grant or deny request for expedited processing within 10 days, and process expedited request as soon as practicable; requestor may seek immediate judicial review of expedited processing denial).

"FOIA, as amended, envisions the courts playing an important role in guaranteeing that agencies comply with its terms." *Elec. Privacy Info. Ctr. v. DOJ*, 416 F. Supp. 2d 30, 37 (D.D.C. 2006). Thus, consistent with the underlying policies of transparency and timeliness, the FOIA gives U.S. district courts the authority to enforce its provisions, and provides a condensed litigation timeline. *See* 5 U.S.C. §552(a)(4)(B). A court may use its equitable powers to require an agency to process documents according to a court-imposed timeline. *See id.* at 38 (noting that "courts have the authority to impose concrete deadlines on agencies that delay the processing of requests meriting expedition"). Moreover, as the D.C. Circuit has recognized, "unreasonable delays in disclosing non-exempt documents violate the intent and purpose of the FOIA, and the courts *have a duty* to prevent [such] abuses." *Id.* at 35 (quoting *Payne*, 837 F.2d at 494) (emphasis added).

Here, the fact that CHD's request sits in a severely backlogged queue does not eliminate the FDA's obligations for timeliness and transparency under the FOIA; nor does it eliminate the need for this Court to enforce those obligations. CHD sought the records on an expedited basis over two years ago; as evidenced by new information, the urgent need for the records continues to grow; the FDA has a significant portion of the records in hand; and the FDA's extended

processing timeline guarantees that the records will be stale by the time they are finally produced. Now that the *Open America* stay has expired, and regardless of the request's queue placement, it is long past time for the FDA to produce the EB-mining records and start processing the rest of CHD's request.

A) The public's need for the safety-monitoring records was urgent when CHD submitted its FOIA request in 2022, and is urgent now.

Since June 2024, when the *Open America* stay in this case expired, the FDA has authorized and approved a new round of COVID-19 booster shots.[12] Current FDA and CDC webpages continue to tout safety, and to urge nearly universal uptake of those boosters.[13] Meanwhile, as discussed above, questions about risk continue to mount as new studies are published. Indeed, a database published by REACT19 (an organization devoted to helping individuals suffering life-altering side effects from COVID-19 vaccines) now lists over 3500 peer-reviewed case reports and studies linking COVID-19 vaccines to a multitude of medical conditions.[14]

As the FDA acknowledged years ago in a different FOIA lawsuit, the FDA's inquiry into and knowledge of potential associations between a drug and adverse events is a matter of public importance. *See Bloomberg L.P. v. United States FDA*, 500 F. Supp. 2d 371, 378 (S.D.N.Y. 2007) (acknowledging public importance of investigation into and knowledge of potential

[12] *See* FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants, at https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently (last accessed Nov. 14, 2024).
[13] *See id.*; *see also COVID-19 Vaccination for People Who are Pregnant or Breastfeeding*, at https://www.cdc.gov/covid/vaccines/pregnant-or-breastfeeding.html (last accessed Nov. 14, 2024); *Staying Up to Date with COVID-19 Vaccines*, https://www.cdc.gov/covid/vaccines/stay-up-to-date.html (last accessed Nov. 14, 2024).
[14] *See* REACT-19's Published Science Database, https://react19.org/science.

association between certain anti-epileptic drugs and suicide-related adverse events). Indeed, it would be disingenuous for the FDA to say otherwise, where members of the public, desiring to make informed medical decisions, depend on the agency to provide the full product-safety information that it possesses.

Here, members of the public—including parents, medical personnel, policymakers, and others—have tremendous need for transparency about the full safety profile of COVID-19 shots, so as to make fully informed medical and policy decisions. The need is heightened by continued, unqualified federal support for COVID-19 vaccination in the face of ongoing and newfound safety concerns, coupled with mounting recognition of COVID-19 vaccine injuries. *See e.g.*, ECF 28, JSR at ¶13 (discussing growing recognition of COVID-19 vaccine injuries); *see also* H.R. 10077, University Forced Vaccination Student Injury Mitigation Act of 2024, introduced 10/29/24, at https://www.congress.gov/bill/118th-congress/house-bill/10077/text.

As in 2022, the public has an urgent need for full transparency about the FDA's efforts to study the risks associated with COVID-19 vaccines, including what the Agency has learned about the extent to which these shots are responsible—or not—for the 1.6-million-plus adverse events reported to VAERS. The public has an urgent need to know what safety signals the FDA has uncovered since it began monitoring the shots through VAERS in 2021; how the Agency has investigated whatever signals it has detected; and what the Agency concluded about the critical question of causation. The FDA has not released the records containing this VAERS-monitoring information in any form, and the public remains in the dark about what those records contain. It is shameful for the Agency to continue touting its monitoring efforts while refusing to disclose the records of those efforts.

In addition to the continuing urgency described above, Dr. Marks in his recent remarks highlighted an additional, *new* basis for urgency: namely, the need for transparency to combat rising vaccine hesitancy, especially in light of the recent election. Indeed, with public trust in the healthcare system plummeting,[15] the need for transparency in public health is greater than ever. In short, immediate, full transparency about the FDA's safety monitoring is essential for vaccine critics and proponents alike.

B) Under the expedited processing provision of the FOIA and under *Open America*, CHD's request is entitled to immediate processing, regardless of its current placement in the relevant processing queue.

Given the urgent need for the records, immediate processing of CHD's request is required by the expedited processing provisions of the FOIA. Moreover, even in the absence of the expedited processing standard, immediate processing is required under *Open America* itself.

The Freedom of Information Act requires an agency to grant "expedited processing" when a "compelling need" for information exists; a "compelling need" exists where (among other possibilities) a requester is primarily engaged in disseminating information and can show there is an urgency to inform the public concerning actual or alleged Federal government activity. *See* 5 U.S.C. §552(a)(6)(E). Review of an agency's denial of a request for expedition is de novo. *Al-Fayed v. CIA*, 254 F.3d 300, 308 (D.C. Cir. 2001).

Here, when FDA issued its boilerplate denial of expedited processing in 2022, it did not dispute that CHD is primarily engaged in disseminating information to the public, and, indeed, CHD's initial FOIA request clearly establishes this status. See ECF 1-1, Exhibits, pp. 7-8. Instead, the FDA denied the existence of urgency. *Id*., p. 16.

[15] *See Trust in Physicians and Hospitals During the COVID-19 Pandemic in a 50-State Survey of US Adults*, by Roy H. Perlis, et al, JAMA Netw. Open, July 31, 2024, at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2821693?resultClick=3.

Contrary to the FDA's conclusory denial, however, the need for records of the Agency's COVID-19 vaccine safety monitoring was urgent in 2022, and it is urgent now, where (1) the safety monitoring is a matter of current exigency to the American public, as evidenced by the federal government's continued authorization and promotion of the shots coupled with ongoing debate and concerns regarding their safety and mounting recognition of COVID-19 vaccine injuries; (2) the consequences of delaying a response will continue to compromise a significant recognized interest—namely, public health, including the public's interest in the potential association between the shots and adverse events; and (3) the request concerns federal government activity—namely, the FDA's monitoring of vaccine safety on behalf of the American public. *See Al-Fayed v. CIA*, 254 F.3d at 310 (articulating three-prong test for urgency); *see also Bloomberg v. FDA*, 500 F. Supp. 2d at 378 (recognizing that delay in producing safety-related records compromises a significant interest, where "the broader recognized interest [is] that of harm to the health of the public. . . if sustained use of the identified [] drug continues without more immediate guidance and information from the FDA").

When a request qualifies for expedited processing, it moves to the front of the relevant processing queue. *See*, e.g., *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 275 (D.C. Cir. 2012) (award of expedited processing moves the plaintiff's requests to the front of the agency's processing queue, and requires that they be processed as soon as practicable); *Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 259-60 (D.D.C. 2005) (same); *see also Protect Democracy Project, Inc. v. United States DOJ*, 498 F. Supp. 3d 132, 144 (D.C. Cir 2020) (citing *Wash. Post v. Dep't of Homeland Sec.*, 459 F. Supp. 2d 61, 76 (D.D.C. 2006)) ("[P]ursuant to the statutory provision mandating expedited treatment, the public's interest in expedited processing of the plaintiff's request outweighs any general interest

that it has in first-in-first-out processing of FOIA requests."). Accordingly, regardless of where CHD's request currently sits in a queue, it should not have to wait until other requests are processed, and instead, is entitled to processing "as soon as practicable."

Independently, the Court should order immediate processing because the *Open America* stay in this case has expired, the FDA's request to renew it has not been granted, and the FDA's response to CHD's FOIA request is long overdue. When an *Open America* stay is denied or expires, a Court should order the defendant to start processing the request at issue, *regardless* of where the request sits in the relevant processing queue. *See Treatment Action Grp. v. FDA*, 2016 U.S. Dist. LEXIS 127877, *4-44 (D. Conn. 2016) (when *Open America* Stay is denied, court may order immediate or rolling production of records, and may set a deadline for production or require status reports regarding expected processing deadlines); s*ee also Elec. Privacy Info. Ctr. v. FBI*, 933 F. Supp. 2d 42 (setting immediate deadlines for processing documents); *Bloomberg*, 500 F. Supp. 2d 371 at 374 (giving FDA a "75-day period within which the Government is to produce the requested disclosures" regarding anti-epileptic drugs); *Daily Caller News Found. v. FBI*, 387 F. Supp. 3d 112, 121 (D.C. Cir 2019) (ordering parties to agree to rolling production and deadline for completion of production).

Indeed, if in the absence of an *Open America* stay a court defers to an agency's delayed processing timeline rather than ordering timely processing of a request, the *Open America* legal standard becomes pointless, because a defendant can obtain a *de facto* stay simply by maintaining a backlogged processing queue, as in the instant case. So, for example, in *Buc v. FDA*, after the Court denied an *Open America* stay—and despite the fact that the plaintiff's FOIA requests were behind hundreds of other requests in the relevant processing queues—the Court ordered, "in light of the FDA's failure to establish its right to the relief sought and the fact

that the FDA has already taken for itself a period of time far in excess of the statutory default to discharge of its obligations, the Court shall require the FDA to begin processing Plaintiffs' outstanding requests immediately." *Buc v. FDA*, 762 F. Supp. 2d 62, *Id*., 63, 65-66 (D.D.C. 2011).

As in *Buc*, the FDA has in the instant case "already taken for itself a period of time far in excess of the statutory default to discharge of its obligations." *See* 726 F. Supp. at 63. Moreover, without this Court's intervention, the FDA plans to wait for another two to three years before processing CHD's request. The FDA's proposed timeline makes a mockery of both FOIA time limits, and of the legal standard for an *Open America* stay.

The FDA itself has acknowledged that an order for immediate processing of CHD's request would not be unusual for FOIA litigation, regardless of where the request sits in a processing queue. In FDA's original Motion to Stay pleadings, the Agency explained, "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." ECF 20, Defendant's Reply in Support of a Stay, p. 21.

Conclusion and Proposed Order

The FDA's proposed 5-year delay from the date of CHD's FOIA request to the beginning to processing is contrary to the FOIA statute and case law. Here, where CHD's request qualifies for expedited processing, where the *Open America* stay is no longer in effect, and where the request has remained unfulfilled for over two years, this Court should require FDA to process the request now, regardless of where it sits in the queue.

For the foregoing reasons, CHD respectfully requests that the Court order the following: Within 30 days of this order, Defendant shall do the following:

(1) Produce to Plaintiff the 150 EB data-mining records already identified as responsive to Plaintiff's request;

(2) Conduct all searches necessary to fulfill the remainder of Plaintiff's request;

(3) Submit a status report to this court, detailing the following:

(a) Whether the EB-mining records have been produced;

(b) What searches have been conducted;

(c) The volume of responsive records located;

(d) A proposed production schedule for the responsive records;

(e) Whether Plaintiff agrees with the proposed production schedule.

Respectfully submitted this 21st day of November, 2024, by

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