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 OPPOSITION TO DEFENDANT'S MOTION TO STAY

For the reasons discussed in Plaintiff's Memorandum of Law in Support of Plaintiff's Opposition to Defendant's Motion to Stay, Plaintiff hereby opposes Defendant's Motion for an Eighteen-Month Stay of Proceedings and respectfully requests that this Court deny the motion.

Date: October 11, 2023

Respectfully submitted,

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO STAY

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INTRODUCTION

Since the fall of 2020, over 1.5 million adverse events following receipt of a COVID-19 injection have been reported to the Vaccine Adverse Events Reporting System ("VAERS"). Which of these adverse events were caused by the shots, and which were caused by something else? For the most part, VAERS does not answer those questions directly. But since early 2021, Defendant the United States Food and Drug Administration (the "FDA") has been using Empirical Bayesian ("EB") data mining to look for statistical signals in VAERS that indicate possible causal relationships between COVID-19 injections and adverse events reported to VAERS. When a safety signal is detected, the FDA works with the Centers for Disease Control and Prevention ("CDC") to conduct follow-up investigation. In addition, when certain types of serious adverse events of special interest ("AESIs") are reported to VAERS, the agency is supposed to review medical records collected for the individuals who experienced those events.

In July 2022, Plaintiff Children's Health Defense ("CHD") submitted a Freedom of Information Act ("FOIA") request to the FDA seeking records of the FDA's efforts to mine VAERS for safety signals related to COVID-19 injections, to investigate any signals uncovered, and to review reports of AESIs.

CHD filed the instant lawsuit in January 2023, after the FDA denied CHD's FOIA request outright and indicated that it would not rule on CHD's administrative appeal for another 9-12 months. After the lawsuit was filed in the spring of 2023, the FDA indicated that it had located 150 records related to the EB mining, including 75 excel files and 75 pages of emails. But to date, the FDA has refused to produce these records and the agency has not located any other of the records sought in CHD's request.

The FDA does not dispute that CHD's 14-month-old FOIA request is legally entitled to processing under FOIA and the agency's regulations. Nor has the agency ever indicated that the request is unclear, overbroad, or burdensome, or asked CHD to narrow the request. Now, however, FDA seeks to halt all processing of the request—including production of the 150 EB-mining-related records—until April 2025 at the soonest.

The Center for Biologics Evaluation and Research ("CBER") is the center within the FDA that regulates biological products for human use, including vaccines; when FDA receives a FOIA request for CBER-maintained records, it assigns that request to a sub-division within CBER—the Access Litigation and Freedom of Information Branch ("ALFOI"). The FDA argues that the Court should suspend all of the agency's FOIA duties to CHD for at least eighteen months because ALFOI is struggling to shoulder its current FOIA workload and does not have the "bandwidth" to process CHD's request. *See* ECF 17-1, Memorandum in Support of defendant's Motion for an Eighteen-Month Stay of Proceedings, pp. 1, 9-12; ECF 17-2, Declaration of Suzann Burk, ¶ 31. To support this argument, FDA points to the fact the annual number of FOIA requests assigned to ALFOI has increased since 2019, and the handful of ALFOI personnel processing these records also must keep up with the hefty production schedule for COVID-19 vaccine licensing information that was ordered by the United States District Court for the Northern District of Texas in the *Public Health and Medical Professionals for Transparency* ("PHMPT") litigation. *See generally*, *Pub. Health & Med. Pros. For Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT 1*") and *Pub. Health & Med. Pros. For Transparency v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT 2*") (together, "*PHMPT Litigation*"). However, FDA's exclusive focus on ALFOI-related FOIA metrics hides a conclusion that becomes inescapable when a broader view is taken: namely, that any challenge

ALFOI faces in managing its current workload is a problem of the FDA's own making.

The Freedom of Information Act requires an agency such as the FDA to produce documents "promptly" in response to a properly formulated request. And while an agency is free to assign the *work* of responding to FOIA requests to a sub-division within the agency, the *responsibility* for FOIA compliance, including the responsibility to meet FOIA time limits, lies squarely with the agency itself.

Here, according to agency FOIA reports, the overall number of FOIA requests received by the FDA each year in 2020, 2021, and 2022 was lower than in any of the previous six years, while the number of staff working full-time to process FOIA requests within the FDA has risen steadily since 2014. In the meantime, the number of FOIA requests assigned to ALFOI for processing has gone up each year starting in 2019, but the FDA did not start adding to ALFOI's FOIA workforce until 2022. The FDA has a multi-billion-dollar budget and thousands of employees, so with fewer requests to process and more employees to process those requests at the agency level, any bottleneck in ALFOI's work appears to be a result of the FDA's own staffing choices. But instead of fixing the problem, FDA now seeks *carte blanche* to ignore the FOIA altogether: an eighteen-month stay with an unconditional option to renew and no mandate to take any steps towards processing CHD's request in the meantime. The FDA's decision to devote an inadequate portion of its resources to ALFOI does not entitle it to such extraordinary and unprecedented relief.

The FDA argues that the bottleneck at ALFOI entitles the agency to a stay under 5 U.S.C. § 552(a)(6)(C) as interpreted in *Open America v. Watergate Special Prosecution. Force*, 547 F.2d 605 (D.C. Cir. 1976). However, the agency has failed the two required showings for an *Open America* stay: 1) that it is exercising "due diligence" in responding to CHD's FOIA

request; and 2) that it faces "exceptional circumstances."

The FDA has treated CHD's request in derogation of the FOIA from the very start, by denying the request without even searching for records and promising a minimum of nine months to consider CHD's administrative appeal. Although the FDA located 150 EB-mining-related records over 5 months ago, the agency continues to withhold those records to this day. Additionally, the FDA continues to delay search and processing of the other records sought in CHD's request, which cover the FDA's efforts to investigate safety signals detected through the EB mining and to review AESIs. In sum, the FDA's treatment of CHD's request does not qualify as "diligent."

Additionally, the FDA has failed to show that it faces exceptional circumstances. The agency does not face a deluge of requests; indeed, its overall request numbers have gone down, not up, in the last few years. Although more of the agency's requests have been assigned to ALFOI since 2019, the FDA has been aware for over three years that this shift was occurring. Moreover, the agency's current vaccine-related FOIA obligations were entirely predictable, given the FDA's rapid grant of Emergency Use Authorization ("EUA") and then full licensure to some COVID-19 injections, the safety concerns surrounding the shots from the outset, and the FDA's own regulations, which make vaccine licensing information immediately available for public disclosure when a full license is granted.[1]

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[1] The regulation requiring disclosure of licensing information does not apply when the FDA *authorizes* use of a product by granting an Emergency Use Authorization (EUA); an EUA is not a license. Rather, the regulation applies when the FDA *approves* a product, and grants a full license. The difference between emergency use authorization and full licensure is discussed here: *Understanding the Regulatory Terminology of Potential Preventative and Therapeutic Drugs for COVID-19*, Emergency Use Authorization (EUA), U.S. FOOD & DRUG ADMINISTRATION (as of Apr. 13, 2023), https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventative-and-therapeutic-drugs-covid-19#:~:text=The%20process%20for%20issuing%20an,needed%20for%20an%20FDA%20approval.

Any challenge FDA faces in meeting its FOIA obligations is the result of its decision to assign the substantial work of processing vaccine-related FOIA requests to ALFOI without providing ALFOI sufficient staff to shoulder that load. But *Open America* does not allow an agency to punish CHD for the agency's own decisions, particularly since the FDA has ample resources to staff its FOIA operations in a way that allows it to meet its transparency obligations under the FOIA.

Nor is the FDA—having failed to qualify for a stay under the FOIA—entitled to equitable relief under *Landis v. North American Co.*, 299 U.S. 248 (1936). CHD's request for the FDA's VAERS safety-monitoring records has been outstanding for over a year. Absolving the agency of all FOIA duties towards CHD for at least another year and a half will injure CHD and the public, whose need to understand how and why the FDA considers COVID-19 vaccines safe—despite the multitude of adverse events reported to VAERS—has only increased since the request was submitted to the FDA. The FDA does not even acknowledge the harm caused by the agency's continuing failure to respond to CHD's request, let alone weigh that harm. Furthermore, in the absence of a stay, FDA is simply required to process CHD's request in accordance with the law, which does not qualify as a "hardship" to justify equitable relief. Finally, contrary to FDA's assertion, leaving this case on the Court's docket for another year and a half with no end in sight will not promote judicial economy. The real way to promote judicial economy here is for the FDA to comply with its FOIA obligations forthwith.

BACKGROUND

I. CHD's FOIA REQUEST

A. The FDA's Obligation to Monitor VAERS for Safety Signals Connected with COVID-19 Injections

In December 2020, the FDA granted Emergency Use Authorization ("EUA") for Pfizer-BioNTech and Moderna COVID-19 injections.[2] Since then, the U.S. government has engaged in ongoing efforts to promote these shots, spending billions of dollars to purchase them;[3] paying billions of dollars to media and so-called "trusted" sources to promote them;[4] funding broad-based efforts to distribute them;[5] working with social media companies to censor those who question them;[6] and mandating millions of civilians and military personnel across the nation to

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[2] *See* Federal Register/Vol. 86, No. 11 at 5200-5219 (Jan. 19, 2021), https://www.govinfo.gov/content/pkg/FR-2021-01-19/pdf/2021-01022.pdf.

[3] *See, e.g.*, Contract #W15QKN21C0012 Awarded by Department of Defense to Pfizer Inc., *Award Profile, Contract Summary, Definitive Contract, PIID W15QKN21C0012*, USASPENDING.GOV, https://www.usaspending.gov/award/CONT_AWD_W15QKN21C0012_9700_-NONE-_-NONE-; https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf.

[4] *See Text: H.R. 1319 – American Rescue Plan Act of 2021*, 117th Congress (2021-2022), CONGRESS.GOV, https://www.congress.gov/bill/117th-congress/house-bill/1319/text; *see also Campaign Approach to Reaching General Audiences*, Paid Media, WE CAN DO THIS COVID-19 PUBLIC EDUCATION CAMPAIGN, https://wecandothis.hhs.gov/resource/campaign-approach-to-reaching-general-audiences#paid-media.

[5] *See* CDC Press Release, *CDC Awards $3 Billion to Expand COVID-19 Vaccine Programs*, CDC Newsroom, CENTERS FOR DISEASE CONTROL AND PREVENTION (Apr. 6, 2021), https://www.cdc.gov/media/releases/2021/p0407-covid-19-vaccine-programs.html#:~:text=The%20Centers%20for%20Disease%20Control,virus%20that%20causes%20COVID%2D19.

[6] *See, e.g.*, the Fifth Circuit's opinion in *Missouri v. Biden*, No. 23-30445 (Sept. 8, 2023), https://ago.mo.gov/wp-content/uploads/Doc.-238-1-Fifth-Circuit-Opinion.pdf; *see also* the District Court's *Memorandum Ruling on Request for Preliminary Injunction* in *Missouri v. Biden*, No. 3:22-cv-01213 (W. D. La, July 4, 2023), https://storage.courtlistener.com/recap/gov.uscourts.lawd.189520/gov.uscourts.lawd.189520.293.0_1.pdf.

be injected with them.[7]

Numerous medical professionals and other concerned individuals have questioned the safety of COVID-19 injections.[8] However, U.S. public health agencies continue to assure the public that the shots are vigilantly monitored for safety, and that they are, in fact, safe. For example, the CDC states, stating "COVID-19 vaccines are safe and effective" and "[m]illions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history."[9] In a similar vein, on a web page entitled "COVID-19 Vaccine Safety Surveillance," the FDA states, "FDA is conducting intensive monitoring of COVID-19

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[7] *See, e.g.*, *Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees*, THE WHITE HOUSE (Sept. 09, 2021), Executive Order on Covid Safety Protocols for Federal Contractors; *Fact Sheet: Biden Administration Announces Details of Two Major Vaccination Policies*, THE WHITE HOUSE (Nov. 4, 2021) https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/; *Covid-19 Vaccination and Testing; Emergency Temporary Standard*, 86 Fed. Reg. 61402 (Nov. 5, 2021), https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23643.pdf.

[8] *See, e.g.*, Melissa Rudy, Angelica Stabile, *New COVID vaccine push is 'anti-human,' says Florida surgeon general: 'Major safety concern*," FOX NEWS (Oct. 3, 2023), https://www.foxnews.com/health/new-covid-vaccine-push-anti-human-says-florida-surgeon-general-major-safety-concern; Malhotra, Aseem, *Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1*, JOURNAL OF METABOLIC HEALTH [Online], Volume 5 Number 1 (Sept. 26 2022), https://journalofmetabolichealth.org/index.php/jmh/article/view/71/224; Video: *Dr. Peter McCullough Speech at European Parliament*, YOUTUBE, https://www.youtube.com/watch?v=1Pa9yZ9kwc0; *Scientific Publications Directory*, REACT19, https://react19.org/science; *Science in Depth*, DOCTORS FOR COVID ETHICS, https://doctors4covidethics.org/science-in-depth/; Kyle A. Beattie, *750+ Studies About the Dangers of the COVID-19 Injections* (Mar. 31, 2022), https://img1.wsimg.com/blobby/go/058ad340-73c5-4f3d-af4f-8df4795d5196/750-Studies-About-the-Dangers-of-the-COVID-19-.pdf; Video: *Live in D.C.: Expert Panel on Medical Mandates & Vaccine Injuries*, THE HIGHWIRE, https://thehighwire.com/videos/live-in-d-c-expert-panel-on-medical-mandates-vaccine-injuries/.

[9] *Safety of COVID-19 Vaccines*, CENTERS FOR DISEASE CONTROL AND PREVENTION (updated Sept. 12, 2023), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

vaccine safety in the U.S. using a variety of approaches. Based on available information, FDA strongly believes that the known and potential benefits of COVID-19 vaccination greatly outweigh their known and potential risks."[10]

A key part of COVID-19 vaccine safety monitoring in the U.S. is the Vaccine Adverse Reporting System ("VAERS"), which accepts reports of post-vaccination adverse events from members of the public, healthcare professionals, and vaccine manufacturers. VAERS is the "national early warning system to detect possible safety problems in U.S.-licensed vaccines,"[11] and is co-managed by the FDA and the Centers for Disease Control and Prevention ("CDC").[12]

Over 1.5 million adverse events have been reported to VAERS following COVID-19 shots, vastly exceeding the number of adverse events reported for all other vaccines combined over a more than thirty-year period.[13] And while "VAERS reports generally cannot be used to determine if a vaccine caused or contributed to an adverse event or illness,"[14] the CDC explains that,

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[10] *See COVID-19 Vaccine Safety Surveillance*, Summaries of Monitoring Efforts, U.S. FOOD & DRUG ADMINISTRATION (Dec. 7, 2021), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (last accessed Sept. 20, 2023); *see also Safety of COVID-19 Vaccines*, *supra*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

[11] *About VAERS*, VAERS VACCINE ADVERSE EVENT REPORTING SYSTEM, https://vaers.hhs.gov/about.html.

[12] *Id.*

[13] *See generally* OPENVAERS, https://openvaers.com/; *see also VAERS COVID Vaccine Adverse Event Reports*, Covid Vaccine Data, OPENVAERS, https://www.openvaers.com/covid-data; CDC WONDER, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://wonder.cdc.gov/vaers.html; *How to Access VAERS Data through VAERS WONDER System*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/access-VAERS-data.html#:~:text=Go%20to%20https%3A%2F%2Fwonder,box%20to%20start%20your%20search.

[14] *VAERS Overview*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview (current as of Aug. 12, 2021).

> The information collected by VAERS *can* quickly provide an early warning of a potential safety problem with a vaccine. Patterns of adverse events, or an unusually high number of adverse events reported after a particular vaccine, are called "signals." If a signal is identified through VAERS, scientists may conduct further studies to find out if the signal represents an actual risk.[15]

According to the CDC, "[i]f it looks as though a vaccine might be causing a problem, FDA and CDC will investigate further and take action if needed."[16]

The *Vaccine Adverse Event Reporting System* (*VAERS*) *Standard Operating Procedures for COVID-19* (*as of 29 January 2021*) ("VAERS SOP") describes the methods used by the CDC and the FDA to monitor VAERS for potential safety signals in connection with COVID-19 injections.[17] The VAERS SOP states that—among other activities—the two agencies will conduct "routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines;"[18] the CDC will use Proportional Reporting Ratio ("PRR") analysis to look for potential safety signals, and the FDA will perform Empirical Bayesian data mining ("EB mining") to do the same.[19] If the CDC determines that a signal merits further investigation, the agencies will collaborate on that investigation.[20]

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[15] *Vaccine Adverse Event Reporting System (VAERS),* Vaccine Safety, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last accessed October 6, 2023).

[16] *Id.*

[17] *See Vaccine Adverse Event Reporting System* (*VAERS*) *Standard Operating Procedures for COVID-19* (*as of 29 January 2021*), CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf (hereinafter "VAERS SOP"),

[18] *See* VAERS Team, VAERS SOP, at 3.

[19] VAERS SOP, *supra*, at 16; *see generally* Tom T. Shimabukuro, Michael Nguyen, David Martin, Frank DeStefano, *Safety monitoring in the Vaccine Adverse Event Reporting System* (*VAERS*), VACCINE, Volume 33, Issue 36, 2015, 4398-4405, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2015.07.035, https://www.sciencedirect.com/science/article/pii/S0264410X15009822, at 4401, describing how disproportionality analysis such as PRR is used to detect safety signals.

[20] *Id.*

The VAERS SOP states that the FDA will

- Routinely conduct manual review of reports of serious adverse events of special interest ("AESIs") (VAERS SOP at 11, 12, 20);
- Conduct Empirical Bayesian (EB) data mining at least bi-weekly to identify adverse events reported more frequently than expected, and share and discuss results and signals with the CDC (*Id.* at 16-17);
- Receive and discuss the results of the CDC's own PRR data mining, including the results and signals (*Id.* at 17);
- Consult with VAERS staff of the CDC's Immunization Safety Office to coordinate further investigation if a signal is detected (*Id*. at 16-17, 19).

Importantly, it turns out that the FDA's EB mining data is the *only* ongoing federal effort to mine VAERS for safety signals connected with COVID-19 shots. According to the CDC, with the exception of three months in 2022, the agency has not conducted the PRR analysis that is described in the VAERS SOP after all.[21] Instead, the CDC has been relying on the FDA's EB mining to detect safety signals; according to the CDC, this is because EB mining is the "gold standard" and "a more robust data mining technique."[22]

According to CDC, the results from the CDC's brief 2022 PRR analysis were "generally consistent with Empirical Bayesian data mining, revealing no additional unexpected safety signals."[23] Notably, the CDC's PRR analysis—which CDC has released to various organizations, including CHD—revealed myriad safety signals.[24]

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[21] *See Letter from CDC to CHD* dated March 24, 2023, https://childrenshealthdefense.org/wp-content/uploads/1st-Interim-Release-22-02105-FOIA-23-cv-00431.pdf.

[22]*See Letter from CDC to CHD* dated June 9, 2023: https://childrenshealthdefense.org/wp-content/uploads/CDC-Letter-about-PRR-and-EB-mining.pdf*; see also Letter from Sen. Ron Johnson to Rochelle Walensky, MD, MPH* dated January 10, 2023, https://www.ronjohnson.senate.gov/services/files/AB68101B-CDA4-49F1-8174-4274DDEB0120.

[23]*See Letter from CDC to CHD* dated June 9, 2023, *supra.*

[24] *See Letter from Sen. Ron Johnson to Rochelle Walensky, MD, MPH, supra; see also CDC Finds Hundreds of Safety Signals for Pfizer, Moderna COVID Vaccines*, by Epoch Times,

B. CHD's Request for Records of the FDA's VAERS-Related Safety-Monitoring[25]

Plaintiff Children's Health Defense is a non-profit organization comprised of journalists, lawyers, scientists and public health, medical, and other professionals. CHD works to expose causes of health epidemics, eliminate harmful exposures, hold those responsible accountable, seek justice for those injured, and establish safeguards to prevent future harm. CHD disseminates public health information and data via its daily online news publication, website, broadcast media channel, and social media platforms. [26]

As part of its mission, CHD regularly requests records from federal agencies pursuant to the Freedom of Information Act ("FOIA") and makes information gathered pursuant to those requests available to the public.[27] On July 27, 2022, CHD submitted a request for records of the

reprinted in The Defender (Jan. 3, 2023), https://childrenshealthdefense.org/defender/cdc-safety-signals-pfizer-moderna-covid-vaccines-et/; Josh Guetzkow, *CDC Finally Released its VAERS Safety Monitoring Analyses for COVID Vaccines via FOIA*, RESEARCH REBEL (Jan. 4, 2023), https://jackanapes.substack.com/p/cdc-finally-released-its-vaers-safety.

[25] The Complaint in this case included a related FOIA request that CHD submitted to the FDA on September 8, 2022, seeking records of the EB mining underlying a 2021 article about reporting rates for death following COVID-19 vaccination. *See* ECF 1, Complaint, at ¶ 32. The FDA responded to the request in July 2023, producing a single page of records, so the request is no longer an issue in this case.

[26] *See The Defender*, Children's Health Defense News & Views, CHILDREN'S HEALTH DEFENSE, https://childrenshealthdefense.org/defender; Children's Health Defense website, https://childrenshealthdefense.org; CHD.TV, Children's Health Defense Live, Video, Audio, https://live.childrenshealthdefense.org; Children's Health Defense Facebook page, https://www.facebook.com/ChildrensHealthDefense; Children's Health Defense Twitter (X) page, https://twitter.com/ChildrensHD; Children's Health Defense rumble page, https://rumble.com/user/childrenshealthdefense.

[27] *See FOIA*, Legal Justice, Children's Health Defense Law & Resources, CHILDREN'S HEALTH DEFENSE, https://childrenshealthdefense.org/legal_justice/foia/.

FDA's VAERS data mining and follow up investigation conducted pursuant to the VAERS SOP. In relevant part, the request sought the following: [28]

- *Item 2*: Records of any manual review of serious AESI reports conducted by the FDA and/or the Center for Biologics Evaluation and Research ("CBER");
- *Item 3*: Records of any Empirical Bayesian data mining conducted by the FDA and/or CBER, and records of any sharing or discussion of results and signals with the CDC;
- *Item 4*: Records of any results and signals received by the FDA and/or CBER from the CDC's own PRR data mining, and any discussion of those results;
- *Item 5*: Records of any consultations by the FDA and/or CBER with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected.

See ECF 1-1, Exhibits to Complaint for Declaratory and Injunctive Relief, at 5.

CHD included a detailed request for expedited processing, which described the background for the request that is discussed above, and noted the urgent need for the safety-monitoring information, both to help the public make fully informed medical and political decisions and to maintain trust in federal public health agencies. *See id*. at 7-10.

C. FDA'S Pre-Litigation Response to CHD's Request

On August 2, 2022, the FDA acknowledged receipt of the request and assigned it FOIA #2022-5587. *See* ECF 1-1 at 14. The acknowledgment letter did not indicate that the FOIA request was unclear, overbroad, or otherwise improperly formulated, and did not seek clarification or narrowing *See id.* The letter stated that the FDA might be unable to comply with FOIA's twenty-working-day time limit and the additional ten days provided by the FOIA, but did not provide an estimated response date. *See Id.*

[28] The original request included six items, two of which were withdrawn by CHD. For details, *see* ECF 1, Complaint, at ¶¶ 16 and 21. The item numbers above correspond with the numbers in the original FOIA request, and because item 1 in the original request was withdrawn, the list above starts with item 2.

On August 8, 2022, the FDA denied CHD's request for expedited processing, finding—without analysis of CHD's request—a lack of compelling need or urgency. *See ECF 1-1 at* 16.

On October 4, 2022, the FDA issued a determination on the FOIA request. *See* ECF 1-1 at 20-21. The determination letter denied the request *in toto,* claiming a blanket exemption under 5 U.S.C. § 552(b)(5) and associated Department of Health and Human Services (HHS) regulations. *See id.* The letter did not indicate that the agency had searched for responsive records, or applied the "foreseeable harm" standard to potentially exempt material, or attempted to segregate non-exempt records for disclosure. *See id*.

On October 11, 2022, CHD filed an administrative appeal requesting, among other things, that the FDA immediately search for responsive records, and promptly provide all non-exempt records to CHD. *See* ECF 1-1 at 33-37. On October 12, 2022, the FDA acknowledged the appeal and assigned it #22-000123AA. *See Id.* at 22. On November 12, 2022, after CHD inquired about a timeframe for the appeal, the agency indicated that the appeals process would take 9-12 months, with a final response "around" the summer of 2023. *See id*. at 25.

D. FDA's Post-Complaint Processing of CHD's Request[29]

CHD filed its complaint in this Court on January 26, 2023, and the FDA responded on April 4, 2023. *See* ECF 1, Complaint; ECF 11, Answer.

In May 2023, the FDA indicated in lawsuit brought by the Informed Consent Action Network ("ICAN") that it had located 150 records potentially responsive to the request for EB-mining records that ICAN submitted to the agency; these included 75 emails and 75 excel files.

[29] This discussion omits FDA's representations about CHD's September 2022 FOIA request, described above at Footnote 25, because the FDA provided a final response to the request—a single page of records—in July 2023, and the request is no longer an issue in this case. *See* ECF 15 at ¶¶ 5-6.

See Informed Consent Action Network v. FDA, No. 1:23-cv-00219 (D.D.C.), ECF 17, Joint Status Report, at ¶¶ 1, 5 ("*ICAN EB-Mining Litigation*").

On May 12, 2023, CHD and the FDA filed their first Joint Status Report ("JSR"). *See* ECF 13. In the JSR, the FDA represented that it had had "conducted searches for records potentially responsive to certain items" in CHD's request, which it was reviewing for responsiveness, and would "conduct supplemental searches for all four items" in the request, which it was "currently in the process of formulating." *See id*. at ¶ 7. However, because it was "still in the process of conducting searches" and had "not yet determined the volume of potentially responsive records," the agency was unable to provide a processing and production schedule. *Id*. ¶ 8. Accordingly, FDA sought an additional forty-five days, by which time it "anticipate[d] being able to propose a processing and production schedule" and to "report the nature and volume of potentially responsive records to be reviewed and whether the previously denied records contain reasonably segregable portions." *Id*. at ¶¶ 8 and 10.

In the second JSR, filed June 27, 2023, FDA represented that it was "finalizing" its responsiveness and releasability determinations for item 4; had collected 150 records "potentially responsive" to the request for EB data mining and consultations with CDC regarding safety signals; and was still "in the process of conducting" additional searches for items 2, 3, and 5. *See* ECF 14, ¶¶ 3, 5, 6. The FDA stated that "[w]ith searches still underway," it was still unable to propose a processing schedule. *Id*. at ¶ 8. Thus, the agency sought an additional forty-five days "to continue conducting searches that address the remaining items" in the request. *Id*.

In the third JSR, filed August 11, 2023, the FDA represented that the records it located for item 4 are not responsive after all, and the 150 records located for items 3 and 5 are responsive. *See* ECF 15 at ¶¶ 6, 7. These 150 records appear to be the same records that are at

issue in the *ICAN Data-Mining Litigation*. The Agency stated that additional searches for items potentially responsive to items 2, 3, and 5 "have not been completed." *See id*. at ¶ 8. However, rather than conducting those searches, providing the 150 records already located, or providing the timeframe for search, processing, and production promised in the first two JSRs, the FDA now seeks to halt any and all processing of CHD's request.

II. FDA FOIA METRICS FROM 2014 THROUGH 2022

According to the FDA's website, FOIA request for the FDA are submitted to the agency's Division of Freedom of Information.[30] In most cases, after a request is submitted, the Division of Freedom of Information assigns the processing of the request to the "agency component" that maintains the particular records being sought.[31] Thus, for example, a request for vaccine-related records like CHD's is assigned to a division within the Center for Biologics Evaluation and Research ("CBER"), which is the FDA Center that regulates vaccines and other biological products for human use.[32] Within that CBER division (the Division of Disclosure and Oversight Management, or "DDOM"), the request is processed by the Access Litigation and

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[30] *See How to Make a FIOA Request*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request.

[31] *See Frequently Asked Questions (FAQ) for Freedom of Information*, Question 5, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/regulatory-information/freedom-information/frequently-asked-questions-faq-freedom-information#Q5; *see also Whom to Contact About FOIA*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/regulatory-information/freedom-information/whom-contact-about-foia (listing "points of contact" for each FOIA-processing component).

[32] *Center for Biologics Evaluation and Research (CBER) Responsibilities Questions and Answers*, U.S. FOOD & DRUG ADMINISTRATION (current as of Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research-cber-responsibilities-questions-and-answers#:~:text=What%20is%20the%20Center%20for,Food%2C%20Drug%20and%20Cosmetic%20Act.

Freedom of Information Branch ("ALFOI").[33]

While the Freedom of Information Act requires every federal agency to report a variety of FOIA-related metrics at the end of each fiscal year, *see* 5 U.S.C. § 552(e), these are reported for the agency as a whole, rather than for sub-divisions of the agency, such as CBER or ALFOI.[34] Agency-wide FOIA metrics for the FDA from 2014 to 2022, presented in the chart below, show the following:

- the average number of FOIA requests received annually by the FDA was 10,140, with highs of 11,062 requests in 2017 and 11,578 requests in 2019, and lows of 8,529 requests in 2021 and 9,333 requests in 2022;
- the number of staff working on FOIA requests within the FDA has increased each year, from 120.59 full-time-equivalents in 2014 to 162.95 full-time equivalents in 2022;
- the annual cost of processing FOIA requests within the FDA has gone down since 2014, with a seven-fold decrease in 2019;
- the average response time within FDA for processing perfected requests has increased slightly; and
- the backlog of requests and administrative appeals increased in 2021 and 2022.

The metrics in the chart below are taken from annual FOIA reports generated at the U.S. government's central website for FOIA, *Create an Annual Report*, FOIA.GOV, https://www.foia.gov/data.html.

[33] *See* ECF 17-2, Declaration of Suzann Burk, at ¶¶ 2-4, 12.

[34] *See FOIA Annual Reports*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/foia/reports/annual-reports/index.html.

TABLE: FDA AGENCY-WIDE FOIA METRICS 2014-2022

Fiscal Year	Number of Requests Received	Full-Time FOIA Staff	Processing Costs	Avg. Response Time (Days)– Simple Request	Avg. Response Time (Days)– Complex Request	Number of Backlogged Requests at end of FY	Number of Backlogged Appeals at end of FY
2014	10,224	120.59	$31,435,698	24	138	2617	0
2015	9958	138	$33,911,100	18	186	2337	0
2016	10,374	134.8	$33,387,345	17.3	157.6	2248	0
2017	11,062	147.5	$33,996,472	18.7	138.1	2279	0
2018	10,256	155	$35,000,000	13.1	127.5	2666	0
2019	11,578	155	$5,000,000	12	135	3172	0
2020	9951	149	$5,000,000	17	154	2825	N/A
2021	8529	149	$5,010,000	52	186	3577	27
2022	9333	162.95	$5,100,000	42	188	4188	29

ARGUMENT

I. THIS COURT SHOULD DENY THE FDA'S REQUEST TO HALT ALL WORK ON CHD'S REQUEST UNDER 5 U.S.C. § 552(a)(6)(C), BECAUSE THE FDA HAS FAILED TO SHOW "DUE DILIGENCE" AND "EXCEPTIONAL CIRCUMSTANCES."

A. Legal Responsibility for Meeting FOIA Time Limits Lies with the FDA

The Freedom of Information Act obliges a federal agency, upon receipt of a properly formulated request for records, to make non-exempt, responsive records "promptly available." *See* 5 U.S.C. § 552(a)(3)(A). "Timely disclosure of records is . . . essential to the core purpose of FOIA" (Office of Attorney General's *Freedom of Information Act Guidelines* (March 15, 2022)

at p. 3),[35] and "stale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). Indeed, as the *Open America* court recognized, "Excessive delay by the agency in its response is often tantamount to denial." *Open America*, 547 F. 2d 617 (Leventhal, J., concurring).

Accordingly, the FOIA sets forth a detailed timeline for an *agency's* processing of FOIA requests. For example, upon receipt of a request, a responding agency must determine whether to comply with such request and notify the requestor of the determination within 20 business days. 5 U.S.C. § 552(a)(6)(A)(i)). The agency may grant itself an additional 10 days to respond in "unusual circumstances" so long as the agency notifies the requestor of the unusual circumstances and specifies "the date on which a determination is expected to be dispatched." *Id.* Upon receiving notice of an agency's unilateral extension, the requestor has the right to "limit the scope of the request so that it may be processed within" the applicable time limit. 5 U.S.C. § 552(a)(6)(B)(ii). Once an agency determines to comply with a request for records, those records must be made "promptly available" to the requestor. 5 U.S.C. §552(a)(6)(C)(i)). If a requestor appeals an agency decision, the agency must rule on the appeal within 20 business days. 5 U.S.C. §552(a)(6)(A)(ii). If an agency fails to meet the FOIA's time limits, the requestor is permitted to seek relief in federal court without first exhausting administrative remedies. *See* 5 U.S.C. § 552(a)(4)(B); 5 U.S.C. § 552(a)(6)(C)(i).

The FOIA provides a limited "safety valve" from these strict time limits, *see Open America*, 547 F.2d at 617 (Leventhal, J., concurring), but only if the agency is able to show that "although [the defendant agency] is exercising due diligence in responding to [the plaintiff's]

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[35] *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), https://www.justice.gov/media/1212566/dl?inline.

FOIA request, exceptional circumstances prevent it from processing the request within the statutory time limit." *Elec. Frontier Found. v. DOJ*, 517 F. Supp. 2d 111, 115 (D.C.C. 2007); *see also* 5 U.S.C. § 552(a)(6)(C). If both of those conditions are met, a court "may retain jurisdiction and allow the agency additional time to complete its review of the records." U.S.C. § 552(a)(6)(C).

An agency is certainly free to assign the *work* of responding to FOIA requests to subdivisions or individuals within the agency. However, the text of the FOIA statute makes it clear that the ultimate *responsibility* for timely responding to FOIA requests belongs to the agency itself. Thus, while the FDA is free to assign the *work* of processing of all requests for CBER-maintained records (including all vaccine licensing and safety information) to a CBER sub-division, Access Litigation and Freedom of Information Branch ("ALFOI"), the *responsibility* for processing those requests in compliance with the FOIA belongs with the FDA itself. This distinction cannot be ignored.

B. The FDA Has Not Shown Due Diligence in Processing CHD's Request.

To obtain an *Open America* stay, the FDA must show that "it is exercising due diligence in responding to *the* request." *See* 5 U.S.C. § 552(a)(6)(C)(i) (emphasis added). In other words, FOIA requires the agency to show due diligence in responding to the *plaintiff's* request, rather than merely showing diligence in general. Every case cited by FDA in support of its "due diligence" argument illustrates this rule; in each, the reviewing court was willing to grant relief only where the defendant agency showed that it exercised due diligence in responding to the *plaintiff's* request, in addition to any showing that its FOIA-processing efforts were diligent in general. *See Open America v. Watergate Special Prosecution Force*, 547 F.2d at 609 & 612-13 (noting "[t] he Government defense, simply put, is that the FBI has indeed exercised "due

diligence" in handling all informational requests, *including this one*" (emphasis added), and examining details of how agency was processing the plaintiff's request); *Appleton v. FDA*, 254 F. Supp. 2d 6, 7, 9 (D.D.C. 2003) (examining details of how the agency was processing the plaintiff's request and concluding "[t]he declarations . . . attest to a good-faith, diligent effort to process the plaintiff's request pursuant to FDA's first-in, first-out complex track"); *Energy Future Coal v. Off. Of Mgmt. & Budget*, 200 F. Supp. 3d 154, 161-62 (D.D.C. 2016) (examining details of how agency was processing the plaintiff's request and concluding agency was "exercising due diligence in processing Plaintiff's request"); *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 57, 62 (D.D.C. 2018) (examining details of how agency processed the plaintiff's request, including development of a "comprehensive search plan").

In its "due diligence" argument and supporting declaration, the FDA discusses some steps ALFOI has taken to process FOIA requests *in general* and for *other* requesters, but notably fails to discuss the agency's processing of *CHD's* FOIA request *in particular*. *See* ECF 17-1, Memorandum in Support of Defendant's Motion for an Eighteen-Month Stay of Proceedings, at 2, 12-14 (discussing ALFOI's general FOIA-processing efforts and processing of records in other FOIA litigation); ECF 17-2, Declaration of Suzann Burk, at ¶¶ 7–17 and 20–30 (discussing ALFOI's general FOIA-processing efforts as well as efforts in connection with processing requests from Siri law firm). This is not surprising, given the FDA's lack of diligence in processing CHD's request.

The FDA's absence of diligence with respect to CHD's request was evident from the start. After FDA received CHD's FOIA request in the summer of 2022, the agency apparently took a short cut: on October 4, 2022, it denied the request outright, claiming the requested records were exempt from disclosure. *See* ECF 1-1 at 20-21. Based on the FDA's determination

letter, it appears that before denying CHD's request, the agency did not search for responsive records; nor did it apply the "foreseeable harm" standard to portions it believed were exempt, or attempt to segregate non-exempt portions for disclosure. *See id*. Indeed, based on the determination letter, it appears that with respect to CHD's request, the agency violated ALFOI's own processing protocols. *See* ECF 17-2, Declaration of Suzann Burk, at ¶ 13 ("When a request is assigned to a reviewer for processing, the reviewer must search for and collect potentially responsive records from various file locations, including hard copy and electronic filing systems.") The FDA's apparent failure to follow the most basic legal requirements before denying CHD's request was the antithesis of diligence. *See* 5 U.S.C. § 552(a)(3)(A), (C), and (D) (requiring an agency, upon properly formulated request, to "make the records promptly available," and in responding to request, to "make reasonable efforts to search for the records"); 5 U.S.C. § 552(a)(8)(A) (requiring agencies, when some information is exempt, to apply "foreseeable harm" standard before withholding exempt portions, and to determine whether partial disclosure is possible by taking "reasonable steps" to segregate and release nonexempt information); 45 C.F.R. § 5.2(a) (agency will apply foreseeable harm standard, and will segregate and disclose non-exempt information); 45 C.F.R. § 5.28 (agency will inform requester of determination, *including* whether responsive records were located, how much, and whether records are being released in full or in part, or withheld in full; when denying request, agency will provide estimated volume of withheld records; agency will provide access to segregable non-exempt information and indicate where information has been redacted and the exemptions applied); *see also Memorandum for Heads of Executive Departments and Agencies re Freedom of Information Act Guidelines, supra*, https://www.justice.gov/media/1212566/dl?inline at 1 (describing "presumption of openness," including application of "foreseeable harm" standard

and segregation and disclosure of non-exempt records).

CHD appealed the FDA's denial within a week, asking FDA to comply with the FOIA by searching for responsive records and segregating and disclosing non-exempt portions. *See* ECF 1-1 at 33-37. A month later, after inquiry from CHD, the FDA stated the appeal would not be ruled on for nine to twelve months. *See id*. at 25. Kicking the can down the road in this fashion does not qualify as "diligence." *See* 5 U.S.C. § 552(a)(6)(A)(ii) (setting forth general 20-day time limit for determination of an appeal); 45 C.F.R. § 5.63(a) (agency will respond to appeal "within 20 working days after the appeal official designated in your appeal letter receives it").

In May and June 2023, after CHD filed its complaint, the FDA represented in JSRs that it was "in the process of" formulating and conducting searches for records responsive to CHD's request, the very searches that it should have conducted before denying the request in October 2022. *See* ECF 13 ¶¶ 7, 8, and 10; ECF 14 at ¶¶ 3, 5, and 6. In the May 2023 JSR, the FDA represented to CHD and this Court that it expected to be able to report on the volume of records found and propose a processing and production schedule within 45 days. *See* ECF 13 ¶¶ 8 and 10. But to date, the FDA has collected only 150 responsive records, which it refuses to produce. And now, rather than offering to conduct additional searches or at the very least to produce the records it has already collected, the agency seeks to postpone all further processing of the request for at least eighteen months.[36] Again, hardly a model of diligence. *Cf. Open America*, 547 F.2d at 618 ("An effective demonstration of due diligence might in turn depend on whether the agency . . . has been or is now willing to allow partial release of documents rather than conditioning release on complete processing of the request").

[36] As discussed above at footnotes 25 and 29, this lawsuit originally included a second FOIA request, for which FDA produced a single page of material in July 2023.

The FDA's declaration in support of the motion to stay does not provide a satisfactory explanation as to why the agency seeks to put CHD's FOIA request on hold for at least another year and a half while it continues to process other FOIA requests that have been filed since the agency received CHD's request in August 2022. Indeed, FDA's lack of diligence in processing CHD's request is highlighted when compared with the FDA's treatment of other FOIA requests the agency received in the same month. According to the FDA's FOIA logs, in August 2022, FDA received 785 FOIA requests, of which it has closed 668, or 85% of the total. *See* Declaration of Karl Jablonowski, ¶ 5. The average processing time was 1.228 months. *See id.*

According to Suzann Burk, director of DDOM, when ALFOI is assigned a FOIA request, the request is put into one of six queues, from which requests are assigned to reviewers for processing on a "first-in, first-out" basis. See ECF 17-2 ¶ 12. CHD's request was acknowledged by FDA on August 2, which means that of the requests still pending from August 2022, CHD's must be one of the earliest received by FDA, and thus should be among the first processed. The agency has not indicated that it needs at least eighteen months before it will start working on the other requests still pending since August 2022, or that ALFOI needs at least eighteen months before it will start working on the hundreds of other requests the agency has assigned to ALFOI *since* the agency received CHD's request. But through its Motion to Stay, FDA seeks to ensure that CHD is not part of *any* processing queue for at least the next year and a half.

As the D.C. Circuit has recognized, the FDA must have exercised "due diligence" in processing CHD's request *from the outset* in order to qualify for a stay. *Oglesby v. Dep't of the Army*, 920 F.2d 57, 62 n.33 (D.C. Cir. 1990) ("The court [has] authority to allow the agency additional time to examine requested records in exceptional circumstances where the agency was exercising due diligence in responding to the request and *had been since the request was*

received.") (quoting H.R. Conf. Rep. No. 1380, 93d Cong., 2d Sess. 11 (1974)) (emphasis added). Here, it is obvious that the FDA has not exercised *any* diligence in processing CHD's request—at the outset, or at any point along the way. For this reason alone, the Agency is not entitled to an *Open America* stay.

C. The FDA Has Not Shown that It Faces an Unforeseen and Remarkable Number of Requests, or That it Lacks Resources to Meet its Current FOIA Obligations.

Even assuming *arguendo* that the FDA established diligence in responding to CHD's request – which it has not – in order to obtain an *Open America* stay, FDA must also show that it faces "exceptional circumstances," which has two elements. *See Open America*, 547 F.2d at 616. First, the FDA must show that it has been "deluged with a volume of [FOIA] requests for information vastly in excess of that anticipated by Congress." *See id.* Second, the FDA must show that "the existing resources are inadequate to deal with the volume of such requests" within FOIA time limits. *See id.*

In 1996, Congress amended the FOIA to narrow the definition of "exceptional circumstances," providing that that "the term 'exceptional circumstances' does not include a delay that results from a "predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." *Democracy Forward Found.*, 354 F. Supp. 3d at 59 (quoting 5 U.S.C. § 552(a)(6)(C)(ii)). Thus, "it is not sufficient that an agency receives a high number of FOIA requests or has a large backlog of requests to which it must respond. Instead, an agency must show that the number of requests received in the relevant period was truly unforeseen and remarkable." *Id*. *Daily Caller News Found. v. FBI*, 387 F. Supp. 3d 112, 116 (D.C. Cir. 2019).

The number of FOIA requests received each year by the FDA has gone down since 2019, and in 2020, 2021, and 2022, was well below the average number of requests received annually by the agency since 2014. Meanwhile, the FDA's overall FOIA workforce has grown, and its FOIA-processing costs have decreased. So the FDA cannot argue that the *agency* currently faces an unforeseen and remarkable volume of requests, or that the *agency* lacks the resources to meet those obligations. This alone defeats the FDA's claim of "exceptional circumstances."

None the less, the FDA claims that it is entitled to a stay because ALFOI faces a hefty production schedule for disclosing various COVID-19 vaccine licensing records, along with more FOIA requests and lawsuits, and in light of this work, ALFOI lacks the "bandwidth" to fulfill CHD's request. *See* ECF 17-1 at 12-15; ECF 17-2 at ¶¶ 18-27, 31. This claim should be rejected because, as discussed above, the FDA's overall FOIA metrics do not show a deluge or a lack of resources at the agency level. But the claim fails also because it ignores three key points: first, ALFOI's current workload was not unforeseen; second, the FDA bears responsibility for the current conditions in ALFOI, because it has chosen which requests will be assigned to ALFOI and what resources will be allocated to working on those requests; and third, the agency had and has the resources to staff ALFOI to meet the agency's FOIA obligations— whether by adding new staff or contractors or by shifting resources from other FOIA offices within the FDA. Accordingly, even if the "exceptional circumstances" showing could, in theory, be made based on ALFOI's current FOIA workload load rather than on the agency's overall FOIA load, the agency has failed to make such a showing.

The portion of the FDA's overall FOIA workload that is shouldered by CBER/ALFOI has been increasing for over three and a half years, and the FDA could and should have allocated resources accordingly. According to Sarah B. Kotler, Director of the FDA's FOI Division and

coordinator of the FDA's processing of COVID-19-related FOIA requests, the agency has received a "flood" of pandemic-related requests since President Trump declared a COVID-19 emergency on March13, 2020, *See PHMPT 2*, ECF 027-2, Declaration of Sarah B. Kotler, ¶¶ 1, 4. During that time, while the overall number of requests to FDA went down, the number and complexity of requests assigned to ALFOI has increased. *See* ECF 17-2 ¶ 19. So for over three and a half years, the FDA has been aware of the public's keen interest in the agency's pandemic-related activities and of CBER's activities in particular, and aware of the need to shift resources to ALFOI to keep up with ALFOI's increasing FOIA workload.

The production burden ALFOI faces in the *PHMPT Litigation* also is not a surprise, because in addition to FOIAs requirements that all agencies timely disclose properly-requested records, FDA's own regulations provide unambiguous notice that when the FDA approves a vaccine, licensing information must be disclosed quickly and as a matter of course:

> After a license has been issued, the following data and information are *immediately* available for public disclosure *unless* extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA].

21 C.F.R. § 601.51(e) (emphasis added).

In light of this regulation and the FOIA, the FDA has known from the outset that when it gave full licensure to COVID-19 vaccines, the licensing records would be immediately available for disclosure. Similarly, that FDA has known from the outset that it would assign requests for licensing records to CBER, where ALFOI would have to do the work of processing those records, and would need sufficient resources to do that work.

The need for robust staffing of FOIA operations within CBER was confirmed—and its urgency made even more apparent—on August 27, 2021, just a few days after FDA licensed the Pfizer COVID-19 injection for individuals 16 years of age and older,[37] when the group Public Health & Medical Professionals for Transparency ("PHMPT") submitted a FOIA request seeking on an expedited basis most of the licensing information enumerated in 21 C.F.R. § 601.51(e). *See PHMPT 1*, ECF 1, Complaint, at ¶ 33.[38] The urgency was further highlighted on September 16, 2021, when, after the FDA denied expedited processing, PHMPT sued the agency in the Northern District of Texas. *See id.* at ¶ 9. The urgency was highlighted again on January 6, 2022, when the Court denied FDA's request for 75 years to produce the licensing records for the Pfizer 16+ COVID-19 vaccine, and instead ordered production at a rate of 55,000 pages every 30 days. *See PHMPT 1*, ECF 35, Order, at 3. Similarly, FOIA requests for records after the FDA licensed the Moderna shot[39] and the Pfizer shot for children,[40] and the lawsuit filed when those records were not forthcoming, could not have come as a surprise to FDA. *See PHMPT 2*. Nor was the need to staff ALFOI to timely produce those licensing records a surprise. So for over three and a half years, the FDA has been aware of heightened public interest in its pandemic-related

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[37] See *FDA Approves First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMINISTRATION (current as of Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[38] In addition to being available on PACER, the PHMPT litigation documents referenced in this pleading are available on the PHMPT website: *Public Health and Medical Professionals for Transparency*, https://phmpt.org/.

[39] *Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine*, U.S. FOOD & DRUG ADMINISTRATION (current as of Jan. 31, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[40] *FDA Roundup: July 8, 2022*, U.S. FOOD & DRUG ADMINISTRATION (current as of Jul. 8, 2022), https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022.

activities; aware that when it approved COVID-19 injections, it would be required to disclose licensing information in particular; and aware of the need to staff ALFOI accordingly.

In addition to pointing to its obligations in *PHMPT 1* and *2*, FDA suggests that ALFOI's involvement in other FOIA lawsuits contribute to ALFOI's inability to process CHD's request. *See* ECF 17-1 p. 13. Given the increase in FOIA requests assigned to CBER/ALFOI, without sufficient resources to process those requests, an increase in lawsuits is not a surprise. Moreover, the FDA does not provide information about what those lawsuits entail or explain how those litigation obligations might interfere with its ability to process CHD's request. The mere fact that the agency faces obligations in other litigation "is not, in and of itself, sufficient to establish exceptional circumstances." *Elec. Frontier Found*., 517 F. Supp. 2d. at 118.

To prove "exceptional circumstances," the FDA also must show that it lacks the resources to meet its current transparency obligations under FOIA. *See Open America*, 547 F.2d at 616. Here, in fiscal year 2023, the FDA had over 19,000 employees covered by a budget of $8.4 billion (including an increase of $54 million above FY 2022 to provide "support for essential services such as . . . subject matter expertise on FOIA requests."). *Fiscal Year 2023 Budget in Brief* (hereinafter "*Budget*"), U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, https://www.hhs.gov/sites/default/files/fy-2023-budget-in-brief.pdf, at 19, 23. In FY 2022, FDA maintained a FOIA staff of 162.5 full-time equivalents, the highest number of dedicated FOIA employees working at the agency since 2014.

According to the Burk Declaration, prior to the January 2022 production order in *PHMPT 1*, FDA assigned only ten of its 162.5 full-time FOIA staff to work in ALFOI on requests for CBER-maintained records, including records relating to vaccine licensing and safety

information.[41] *See* ECF 17-2, Declaration of Suzanne Burk, at ¶ 18. However, the FDA did not appeal the *PHMPT 1* production order, and after it was issued, CBER hired nine full-time and one part-time contractors to focus primarily on the *PHMPT 1* production. *Id.* at ¶ 24. The FDA did not appeal the May 2023 *PHMPT 2* production order either, but estimates that the *PHMPT 1* production will be done by November 2023, which should leave those contractors free to focus on the *PHMPT 2* production. *See id.* at ¶ 14. Meanwhile, in the Spring of 2023, CBER also hired six additional full-time FOIA employees.[42] *Id*. at ¶ 25. Thus, an equivalent of 25.5 full-time staff now work on FOIA requests within ALFOI.

While the substantial production requirements under *PHMPT 2* may pose a challenge for the relatively small number of FOIA personnel within ALFOI, it is important to remember the size of the FDA's budget and workforce.[43] Thus, if the current ALFOI workforce needs assistance, the FDA certainly has the resources to provide that help.

Of note, the FDA does not claim that it lacks the resources to meet its transparency obligations to CHD in particular. Indeed, the 150 records already collected are 75 data files and 75 pages of emails (which likely are repetitive, cover emails for the data files) that require minimal if any redactions, and could be produced in less time than it took for FDA to write its Motion to Stay. As for the remainder of the request, FDA has not indicated that it is overbroad,

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[41] These included nine regular staff and one branch chief. *See id*.

[42] While the FDA asserts it takes two years to fully train new staff (*id*. at ¶ 30), the contractors who have worked on the *PHMPT 1* production did not have two years of training and yet they have been producing records for close to two years. If they have been able to meaningfully assist with ALFOI's workload prior to a full two years' worth of experience, certainly the more recently hired six FTEs will be able to do that as well.

[43] *See Department of Health and Human Services, Food and Drug Administration Justification of Estimates for Appropriations Committees, Fiscal Year 2023*, U.S. FOOD & DRUG ADMINISTRATION, at pp. 2, 380, https://www.fda.gov/media/157192/download.

burdensome, or any more resource-intensive than the hundreds of other requests currently being processed by the agency.

Here, FDA's current obligations under FOIA were wholly foreseeable, and FDA is capable of meeting those obligations. That the FDA has consciously chosen to dedicate only 162.5 members of its workforce to complying with the FOIA, and a tiny portion of those to FOIA operations within ALFOI, does not entitle the FDA to ignore the Act's requirements. The number of resources an agency dedicates to FOIA requests does not dictate the bounds of an individual's FOIA rights. *See Open America*, 547 F.2d at 621 (Leventhal, J., concurring).

If the FDA is struggling to meet its transparency obligations, the fault lies with the agency, but so does the cure: the FDA can and must staff ALFOI in a way that allows it to fully meet those obligations. In the meantime, *Open America* does not give the agency license to shift the cost of its mistakes to CHD.

II. THIS COURT SHOULD DENY THE FDA'S REQUEST FOR AN EIGHTEEN-MONTH SUSPENSION OF ITS FOIA DUTIES UNDER *LANDIS*.

The FDA argues that even if it fails to qualify for an *Open America* stay because it cannot show both "due diligence" and "exceptional circumstances," this court should use its inherent equitable authority to grant a stay under *Landis*. *See* ECF 17-1, 17. Undoubtedly, "[t]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. North American Co.*, 299 U.S. at 254-55. However, a stay is "an 'intrusion into the ordinary processes of administration and judicial review,'" *Huddleston v. FBI*, Civ. A. No. 20-0447, 2021 WL 1837548, at *2 (E.D. Tex. May 7, 2021) (citing *Nken v. Holder*, 556 U.S. 418, 427 (2009)), and is "not a matter of right, even if irreparable injury might otherwise result." *Id.* (citing *Virginian R. Co. v. United States*, 272 U.S. 658, 672 (1926)). Rather, a stay is "an

exercise of judicial discretion, and the 'party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.'" *Id.* (citing *Ind. State Police Pension Tr. v. Chrysler LLC*, 556 U.S. 960, 961 (2009)). Moreover, a court's stay order "must be supported by 'a balanced finding that such need overrides the injury to the party being stayed.'" *Belize Soc. Dev. Ltd. v. Govt. of Belize*, 668 F.3d 724, 732 (D.C. Cir. 2012) (quoting *Dellinger v. Mitchell*, 442 F.2d 782, 787 (D.C. Cir. 1971)).

When exercising the power to stay a case, a court must "'weigh competing interests and maintain an even balance between the court's interests in judicial economy and any possible hardship to the parties." *Belize Social Dev. Ltd.*, 668 F.3d at 733. Under *Landis*, "the suppliant for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else." *Landis*, 299 U.S. at 255. Furthermore, where the requested stay is indefinite, the suppliant must demonstrate a "pressing need" for the stay, a need that "overrides the injury to the party being stayed." *Belize Soc. Dev., Ltd.*, 668 F.3d at 732 (quotation, citation omitted).

A. *Landis* Does Not Authorize the Sort of Relief Sought by the FDA

Here, as a preliminary matter, *Landis* does not authorize the sort of relief sought by FDA. The FDA does not really seek a "stay of proceedings" at all; rather, it seeks full absolution from FOIA requirements. The FOIA imposes ongoing duties on the FDA, duties that exist in the absence of any court order, and duties that in CHD's case the FDA has been shirking for over a year. *See, generally*, 5 U.S.C. §552. The FDA is now asking the court to suspend those statutory duties altogether for at least eighteen months. The FDA claims that courts have been willing to grant *Landis* stays in other FOIA cases, but does not identify a single FOIA case in which a court granted a suspension of *all* FOIA obligations, with no firm expiration date, no requirement that

the agency produce or even search for a single record during the period of the stay, and no conditions on renewal. *See cases cited* in 17-1, Defendant's Memorandum, at 11-12.

Landis notes that, "the burden of making out the justice and wisdom of a departure from the beaten track l[ies] heavily on the petitioners, suppliants for relief, and discretion [is] abused if the stay [is] not kept within the *bounds of moderation*." 299 U.S. at 256 (emphasis added). The FDA's requested stay is hardly "within the bounds of moderation," and FDA is not entitled to such extraordinary relief. Moreover, even if the type of extraordinary relief sought here is permissible under *Landis* in theory, the FDA has not met the standard for relief in practice.

B. CHD Will Suffer Harm if a Stay is Granted

FDA asserts that CHD will not be injured by a stay of at least eighteen months because CHD "has not articulated a specific need for these documents or a specific urgency." ECF 17-1, Defendant's Memorandum, at 18. This claim evidences the agency's misunderstanding of the FOIA, which requires prompt production of requested documents *regardless* of the use for which they are sought. *See* 5 U.S.C. §552(a)(3)(A). "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H.R. Rep. No. 93-876, at 6271 (1974)). In and of itself, the FDA's ongoing violation of FOIA time-limits is causing injury to CHD.

Additionally, the FDA's claim that CHD has "not articulated" an urgency for the documents is demonstrably 100% false (but by making such a claim, FDA relieves itself of the need to actually discuss the question of urgency). CHD's original FOIA letter included a detailed request for expedited processing, s*ee* ECF 1-1 at 7-10, discussing the public's urgent need to understand what safety signals the FDA has detected through its VAERS monitoring; how those

signals have been investigated; and how the FDA continues to conclude that COVID-19 injections are safe. *Id.* at 10.

The EB mining records sought in CHD's request are the *only* ongoing records of the federal government's attempt to mine VAERS data for possible causal connections between COVID-19 injections and the multitude of adverse events reported to VAERS after those injections. This information about possible causal links between COVID-19 injections and adverse events remains important for members of the public, who are still faced with decisions about whether to take COVID-19 vaccines and boosters, whether to vaccinate their children, and whether to politically support vaccine mandates. The information also is important for individuals who have suffered adverse events following COVID-19 vaccination and are looking for answers to questions such as "why did this happen?" The information is important for physicians and medical organizations determining what recommendations to make to patients.

The federal government continues to assure the public that COVID-19 injections are safe, and continues to encourage all members of the public to take the latest version of the shots. But as CHD noted in its request for expedited processing, "[a] lack of transparency about how FDA has made good on its promises of safety monitoring both deprives people of the information needed to make fully informed medical and political decisions, and erodes confidence in the conclusions reached and guidance promulgated by the federal government and its agencies." ECF 1-1, Exhibits, p. 10.

The need for this EB-mining data and related information, and the harm that will be caused by postponing disclosure for at least another year and a half, is also evidenced by the fact that the FDA has received (and denied) at least two other FOIA requests for the EB mining records—one from the Informed Consent Action Network, and one from the Epoch Times. *See*

Zachary Stieber, *EXCLUSIVE: FDA Refuses to Provide Key COVID-19 Vaccine Safety Analyses*, THE EPOCH TIMES (Sept. 10, 2022) https://www.theepochtimes.com/article/exclusive-fda-refuses-to-provide-key-covid-19-vaccine-safety-analyses-4722586; *see also ICAN EB-Mining Litigation*, ECF 1, Complaint. Additionally, the FDA received a request for EB mining records from Sen. Ron Johnson, which it also denied, citing "pending litigation." *See* Zachary Stieber, *EXCLUSIVE: FDA Refuses to Provide COVID-19 Vaccine Safety Data to U.S. Senator*, THE EPOCH TIMES (Sept. 7, 2023), https://www.theepochtimes.com/health/exclusive-fda-refuses-to-provide-covid-19-vaccine-safety-data-to-us-senator-5487300. The fact that CHD is joined by three other requesters in seeking EB-mining-related information points to its public importance. *Accord* 5 U.S.C. § 552(a)(2)(D) (requiring each agency to make publicly available in electronic format copies of all records that have been requested three or more times).

The FDA also asserts that CHD will not be injured by a stay because information about Comirnaty and Spikevax injections is already available through the *PHMPT 1* production and on two FDA webpages. ECF 17-1 at 18-19. However, the licensing records produced in *PHMPT 1* do not replicate the records sought by CHD, which include in-depth, ongoing statistical analysis of VAERS, follow-up investigation of safety signals, and manual review of reports connect with AESIs. While the two webpages FDA cites in its pleading discuss dosing and other matters, these webpages also have nothing to do with the ongoing safety-monitoring records. In sum, the sources cited by the FDA do not reduce the injury to CHD caused by FDA's continuing failure to provide the requested records.

C. The FDA Has Failed to Show Sufficient Hardship to Justify a Stay

In addition to ignoring the injury to CHD that would result from a stay, the FDA has failed to demonstrate a clear case of hardship to itself if the Court denies the agency's request to

stop working on CHD's request for another year and a half. Nor has FDA demonstrated a "pressing need" for the stay. At best, the agency has claimed a tangential and highly speculative possibility of harm.

Much of the FDA's Memorandum in Support of a Stay focuses on the hardship caused by the production requirements of *PHMPT 1* and *PHMPT 2*. *See, e.g.*, ECF 17-1 at 4-5 ("Here, FDA can show specific and unprecedented hardships from *PHMPT 1* and *PHMPT 2*"). But the question is not whether the production requirements of *PHMPT 1* and *2* pose a hardship; those requirements and any hardship they cause will remain unchanged regardless of whether or not the Court grants a stay in *this* case. The question is whether in *this* case, requiring FDA to follow the law and process CHD's FOIA request poses a hardship.

The FDA claims that if the agency is required to process CHD's FOIA request, it "may not be able to conduct a line-by-line review of all records to protect confidential information and may be at risk of violating court orders, which would subject the agency to the threat of sanctions." *See* ECF 17-1, Defendant's Memorandum in Support of Motion to Stay, at 17-18. In other words, FDA argues that somehow CHD's request might be the straw that breaks the camel's back and, if required to follow the law in CHD's cases, the FDA might have to violate the law in *PHMPT 2*. Why does CHD's request have such weighty status? The FDA doesn't say. The agency has never indicated that the request is unclear, overbroad, or burdensome, or asked CHD to narrow the request, and FDA's searches to date have yielded only 150 pages of responsive records—EB mining spreadsheets and emails, which could be fully reviewed and produced in a few hours at most. Nor has the FDA indicated that the rest of CHD's FOIA request poses any special challenge. Indeed, FDA points to nothing about processing CHD's request that exceeds the challenge posed by any of the other hundreds of FOIA requests pending with FDA,

and points to nothing that justifies stopping all work on CHD's request while the agency continues to process those other requests.

Being required to follow the law and to process CHD's FOIA request simply does not qualify as the type of "hardship" that justifies an equitable stay. Additionally, the mere fact that FDA is required to defend itself in this FOIA lawsuit does not constitute a clear case of hardship or inequity. *See Lockyer v. Mirant Corp*., 398 F.3d 1098, 1112 (9th Cir. 2005).

D. The FDA Has Failed to Show a Stay Furthers the Orderly Cause of Justice

FDA claims that a *Landis* stay will promote judicial economy because the FDA is not currently able to "agree to a processing schedule" and by April 2025 the agency will be "better situated to update the Court on its ability to process any responsive records in this case." *See* ECF 17-1, Defendant's Memorandum in Support of Motion to Stay, at 19. But keeping this case lingering on the Court's docket for at least another year and a half—with no obligation for the defendant to do anything in the meantime, no standard for ending the stay, and no resolution in sight—will not promote judicial economy.

CONCLUSION

For the reasons above, CHD respectfully requests that the Court deny the FDA's requested stay, and order the FDA to immediately produce the 150 responsive records it has already collected and to complete the remaining processing of CHD's request within thirty days.

Should the Court grant the FDA a longer period to process the request, CHD respectfully requests that the Court order the FDA to make interim releases of material responsive to CHD's request every four weeks, starting with immediate production of the 150 records already collected, and to regularly report its progress to the Court.

Date: October 11, 2023

Respectfully submitted,

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