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. 23-2316 (TJK)

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO STAY

For the reasons discussed in Plaintiff's attached Memorandum of Law in Support of Plaintiff's Opposition to Defendant's Motion to Stay, Plaintiff hereby opposes the Motion to Stay, and respectfully requests that this Court deny the Motion.

Date: November 13, 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, a multitude of medical providers, scientists, and other individuals have expressed serious, well-founded concerns about the dangers posed by COVID-19 injections. During this time, however, the U.S. Government has continued to promote these injections as "safe," and has promised that federal public health agencies are vigilantly monitoring their safety. Along these lines, in early 2021, Defendant the United States Food and Drug Administration (the "FDA") began an active safety-monitoring program aimed at investigating possible causal links between COVID-19 shots and certain "adverse events of special interest" (AESIs).[1]

In September 2022, Plaintiff Children's Health Defense ("CHD") submitted a Freedom of Information Act ("FOIA") request to the FDA seeking records from the FDA's active monitoring program. More than a year later, the FDA has not begun to process CHD's FOIA request. *See* ECF 11-1, Memorandum in Support of Defendant's Motion for an Eighteen-Month Stay of Proceedings, at 19. The FDA does not dispute the 14-month-old request is legally entitled to processing under FOIA and the agency's own regulations. Nor has the FDA ever indicated that the request is unclear, overbroad, or burdensome, or asked CHD to narrow the request. Now, however, the FDA asks this Court to suspend all of the agency's FOIA duties towards CHD for at least eighteen months.

CHD's FOIA request is currently pending in a "complex processing queue," one of six queues maintained by the Access Litigation and Freedom of Information Branch ("ALFOI"),

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[1] *See CBER Surveillance Program, COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol*, U.S. Food & Drug Administration Center for Biologics Evaluation and Research Office of Biostatistics and Epidemiology, BESTINITIATIVE.ORG (Feb. 10, 2021), https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf at p. 6 (last accessed October 24, 2023).

which is the FOIA-processing subdivision of the FDA Center that regulates vaccines (the Center for Biologics Evaluation and Research, or "CBER"). The FDA argues that the Court should suspend all of the agency's FOIA duties to CHD until April 2025 at the soonest because ALFOI is struggling to shoulder its current FOIA obligations, and lacks the "bandwidth" to process CHD's request. *See* ECF 11-1, at 1-2, 8-10; ECF 11-2, Declaration of Suzann Burk, ¶ 31. To support its proposed delay, the FDA points to the fact that 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, the FDA's exclusive focus on ALFOI-related FOIA metrics hides a conclusion that becomes inescapable when a broader view is taken: namely, that the 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. Based on the distribution of ALFOI's FOIA backlog, it appears that the bulk of the new work is in ALFOI's complex processing queue, whose FOIA request backlog exceeds that of all other ALFOI queues combined. Despite this, the FDA did not start adding to ALFOI's FOIA workforce until 2022, and it appears that the number of FOIA personnel working to process requests from the complex queue is miniscule. 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 budget and staffing decisions within the agency.

Instead of fixing the problem and distributing staff sufficient to respond to FOIA requests, 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. But the FDA's decision to devote inadequate resources to ALFOI, and within ALFOI, to allocate work and personnel in a way that effectively turns the complex processing queue into a black hole, does not entitle FDA to such extraordinary and unprecedented relief.

The bottleneck in ALFOI's complex queue does not entitle the agency to a stay under 5 U.S.C. § 552(a)(6)(C) (a.k.a. an *Open America* stay), because the agency has failed the two requisite showings for such a stay: 1) that it is exercising "due diligence" in responding to CHD's FOIA request; and 2) that it faces "exceptional circumstances." *See Open America v. Watergate Special Prosecution. Force*, 547 F.2d 605 (D.C. Cir. 1976).

First, the FDA has not taken a single step towards processing CHD's request even though

fourteen months have passed since CHD submitted its request to the FDA—during which the FDA has processed thousands of other requests, including many that were submitted after CHD's. This is not surprising, since the FDA has chosen to dedicate an anemic portion of its workforce to processing an increasing load of complex requests within ALFOI. Such treatment does not qualify as "diligent," rather, quite the opposite.

Additionally, the FDA has failed to show that it faces exceptional circumstances, the second requirement to obtain an *Open America* stay. The agency does not face a deluge of requests; indeed, its overall request numbers have gone down, not up, since 2019. Although more of the agency's FOIA requests have been assigned to ALFOI since 2019, the FDA has been well aware that this shift was occurring, and aware of the need to obtain and allocate resources accordingly. Moreover, the agency's current vaccine-licensing-related disclosure 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 and controversy 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.[2] Thus, the FDA has been specifically aware of the need to obtain and allocate resources so as to meet these specific transparency obligations.

[2] 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 the FDA faces in meeting its FOIA obligations is the result of its decision to assign the substantial work of processing complex, 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 active safety-monitoring of COVID-19 injections 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 overwhelming number of serious adverse events reported to the Vaccine Adverse Events Reporting System ("VAERS") and elsewhere—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. Needless to say, a federal agency having to comply with the law 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 Promise to Actively Monitor the Safety of COVID-19 Injections

In December 2020, the FDA granted Emergency Use Authorization ("EUA") for Pfizer-BioNTech and Moderna COVID-19 injections.[3] Since then, the U.S. government has engaged in ongoing efforts to promote these shots, spending billions of dollars to purchase them;[4] paying billions of dollars to media and so-called "trusted" sources to promote them;[5] funding broad-based efforts to distribute them;[6] working with social media companies to censor those who question them;[7] and mandating millions of civilians and military personnel across the nation to

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[3] *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.

[4] *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.

[5] *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.

[6] *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.

[7] *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.[8]

Numerous medical professionals, scientists, and other concerned individuals have questioned the safety of COVID-19 injections.[9] Over 1.5 million adverse events have been reported to the Vaccine Adverse Events Reporting System ("VAERS") following the rollout of the COVID-19 shots, vastly exceeding the number of adverse events reported for all other vaccines combined over a more than thirty-year period. The VAERS system includes reports of over 300,000 serious adverse events, and over 36,000 deaths following COVID-19 injections.[10]

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[8] *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.

[9] *See, e.g.*, *Provider Alert: Florida State Surgeon General Issues New Guidance for Recently Approved COVID-19 Boosters*, FLORIDA DEPARTMENT OF HEALTH, Oct. 23, 2023 Bulletin, https://content.govdelivery.com/accounts/FLDOH/bulletins/37742d3; *Cardiac side effects of RNA-based SARS-CoV-2 vaccines: Hidden cardiotoxic effects of mRNA-1273 and BNT162b2 on ventricular myocyte function and structure*, BRITISH JOURNAL OF PHARMACOLOGY, Oct. 12, 2023, doi: 10.1111/bph.16262, https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bph.16262; 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/.

[10] *See* Search Results for Deaths associated with COVID-19 Vaccine, National Vaccine Information Center, medalerts.org (as of 10/27/23) https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=COVID19&VAX[]=COVID19-2&DIED=Yes; Search Results for Serious Adverse Events associated with COVID-19 Vaccine,

In a similar vein, data from the CDC's smartphone-based V-Safe monitoring system through September 2022 show over 3 million individuals reporting adverse health impacts after receipt of a COVID-19 injection.[11]

Despite these reports and concerns, U.S. public health agencies continue to assure the public that COVID-19 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."[12] Similarly, on a web page entitled "COVID-19 Vaccine Safety Surveillance," the FDA states, "FDA is conducting intensive monitoring of COVID-19 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."[13]

National Vaccine Information Center, medalerts.org (as of 10/27/23); https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&SERIOUS=ON; *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.

[11] *See* V-SAFE DATA, V-safe Covid Vaccine Adverse Health Impacts, https://icandecide.org/v-safe-data/; *see also Breaking News: ICAN obtains CDC V-Safe Data*, icandecide.org (Oct. 3, 2022), https://icandecide.org/press-release/breaking-news-ican-obtains-cdc-v-safe-data/ .

[12] *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.

[13] *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.

The FDA's COVID-19 Vaccine Surveillance webpage states that the FDA is engaging in "passive" and "active" surveillance of COVID-19 shots.[14] Passive surveillance includes "unsolicited reports that are sent to a central database or health authority," such as VAERS.[15] In contrast, active surveillance "involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems," which may be used both to "verify signals identified through passive surveillance" and to "detect additional safety signals that may not have been reported as adverse events to passive surveillance systems."[16] According to the FDA, "[a]ctive monitoring is essential because it allows us to assess potential associations between vaccine exposure and adverse events in near-real time, determine if more comprehensive analyses should be conducted, and provide timely information to support regulatory decision-making processes."[17]

The FDA's active surveillance includes a program described in CBER's February 10, 2021 "COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol" (the "*Protocol*").[18] According to the *Protocol*, the FDA will "monitor the rates of various adverse events of special interest (AESIs) following COVID-19 vaccination in near real-time following

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[14] *See COVID-19 Vaccine Safety Surveillance*, Summaries of Monitoring Efforts, *supra*, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance.

[15] *Id*.

[16] *Id*.

[17] See *CBER Surveillance Program, COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol*, U.S. Food & Drug Administration Center for Biologics Evaluation and Research Office of Biostatistics and Epidemiology, BESTINITIATIVE.ORG (Feb. 10, 2021), https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf, ("*Protocol*") p. 6 (last accessed October 24, 2023).

[18] *See id.*

authorization or licensure."[19] The *Protocol* notes that "[p]otential safety outcome risks of COVID-19 vaccines may not be captured in clinical trials, particularly for rare outcomes," and "[p]ost-market active monitoring and reporting of COVID-19 vaccine-related AESIs enables better capture of rare safety outcome risks . . ."[20]

According to the *Protocol*, through "active monitoring in large healthcare databases including insurance claims databases,"[21] the program will "use the observed rates of these outcomes, as data accrue, to identify whether there is a potential increased risk of AESIs following vaccination compared to a control baseline."[22] While this approach "allows for faster detection of a statistically significant association between an exposure and an adverse event," results must be "further investigated and verified" in order to determine whether such association indicates an increased risk of the adverse event.[23] Accordingly, "[i]f a potential signal for increased risk is identified by the active monitoring, we will conduct more extensive analyses to determine if there is a plausible relationship between COVID-19 vaccination and the AESI in question,"[24] including post-signal data quality assurance, signal characterization (*i.e.*, monitoring over time, and assessment for geographic or temporal patterns), additional inferential safety analyses, and potentially, review of medical records in representative cases.[25]

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[19] *See id.*, p. 6.

[20] *See id.*

[21] *See id.*, pp. 6-9. The databases include both Medicare FFS and private insurance claims databases. *Id.*, p. 9.

[22] *See id.*, p. 6.

[23] *See Id.*

[24] *See Id.*

[25] *See Id.*, pp. 25-26.

Addenda to the *Protocol* (the "*Protocol Addenda*") describe similar adverse event monitoring and analysis with respect to COVID-19 booster shots,[26] and COVID-19 shots for children.[27]

B. CHD's Request for Records of the FDA's Active Safety Monitoring Program

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. [28]As part of its mission, CHD regularly requests records from federal agencies pursuant to the Freedom of Information Act ("FOIA") and makes

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[26] *See ADDENDUM, COVID-19 Vaccine Safety Surveillance: Active Monitoring Protocol, CBER Surveillance Program, Biologics Effectiveness and Safety Initiative* (*BEST*), Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV), BESTINITIATIVE.ORG (May 27, 2022), https://bestinitiative.org/wp-content/uploads/2022/06/C19-Booster-Active-Monitoring-Protocol-Addendum-2022.pdf (Addendum describing monitoring in connection with third or booster dose administration among adults ages 18 and older).

[27] *See ADDENDUM, COVID-19 Vaccine Safety Surveillance: Active Monitoring Protocol Addendum, CBER Surveillance Program, Biologics Effectiveness and Safety Initiative (BEST)*, Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV), BESTINITIATIVE.ORG (Apr. 12, 2022), https://bestinitiative.org/wp-content/uploads/2022/04/C19-Active-Monitoring-Protocol-Addendum-2022.pdf (Addendum describing monitoring of AESIs among children between ages of 5 and 17 years) (last visited July 24, 2023).

[28] *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.

information gathered pursuant to those requests available to the public.[29]

On September 7, 2022, CHD submitted a FOIA request to the FDA seeking records in connection with the safety-monitoring conducted by FDA under the *Protocol* and the *Protocol Addenda*. *See* ECF 4, Complaint, ¶ 11; ECF 10, Answer, ¶ 11. The request sought the following records for each (a) data source studied, (b) COVID-19 vaccine brand studied, (c) age group studied, and (d) AESI studied:

A) Descriptive summaries of observed rates of AESIs, described in section 4.5 on pages 12-13 of the *Protocol*;

B) Records of the sequential analyses of AESIs described in section 4.6 on pages 13-24 of the *Protocol* (including both PMaxSPRT and BMaxSPRT);

C) Records of any discrepancies discovered through the quality assurance described in section 4.7 on page 24 of the *Protocol*, and of any follow-up investigation conducted into those discrepancies;

D) For any safety signal that was detected, records of any signal verification that was conducted as described in section 4.8 on pages 24-26 of the *Protocol*.

See ECF 4, Complaint, ¶ 12; ECF 1-1, Exhibits, Ex. 1.

The request sought expedited processing, noting the Federal Government's ongoing efforts to promote COVID-19 vaccination, the limited safety-data available from the clinical trials, the ongoing public weighing of the risks and benefits of the injections, and the ongoing public debate about vaccination policy. *See* ECF 4, Complaint, at ¶ 13; ECF 1-1, Exhibits, Ex.1. The request argued, "The public has an urgent need to understand how the FDA, a Federal Government agency, has followed through on its promise to vigilantly monitor the safety of COVID-19 vaccines. The public has an urgent need to know what safety signals the FDA has uncovered and how those signals have been investigated. The public has an urgent need to understand how the FDA continues to reach its conclusion that the COVID-19 vaccines are

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

safe." *Id*.

C. FDA's Processing of CHD's Request

On September 9, 2022, the FDA acknowledged CHD's FOIA request, assigning it #2022-6494. The acknowledgment indicated "we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA." *See* ECF 4, Complaint, ¶ 14; ECF 10, Answer, ¶ 13. The acknowledgment did not indicate the FOIA request is unclear, overbroad, or otherwise improperly formulated, nor did it ask CHD to narrow the request. *See* ECF 4, ¶ 14. On September 14, 2022, FDA denied CHD's request for expedited processing. *See id.*

On October 12, 2022, CHD emailed FDA requesting a final determination, or else a date certain by which a final determination would be forthcoming. FDA did not respond to the email. *See id.*, ¶ 15; ECF 10, Answer, ¶ 15.

On November 18, 2022, CHD sent a follow-up email to FDA, requesting the same. FDA did not respond to the email. *See* ECF 4, ¶ 16; ECF 10, ¶ 16.

On May 11, 2023, CHD communicated with a FOIA "point of contact" at CBER. The contact indicated that the request is clear and requires no further clarification. The contact also indicated the request is in the FDA's "complex" queue and would not be assigned for processing for at least twenty-four months. *See* ECF 4, ¶17; ECF 10, ¶17.

On August 10, 2023, CHD filed the instant lawsuit. ECF 4. In the FDA's answer, the agency admitted that it has not released any records, but "avers that it continues to process the request." ECF 10, ¶18. This claim is belied by the FDA's own motion papers. The FDA's Memorandum in Support of an Eighteen Month Motion to Stay makes it clear that the FDA has not performed any work at all to process the request. *See* ECF 11-1, pp. 8, 19. Specifically, the agency "has not

identified custodians or search terms, commenced a search, or reviewed any records potentially responsive to Plaintiff's FOIA request." *Id*., p. 19.

II. FDA FOIA METRICS FROM 2014 THROUGH 2022

A. Agency-Wide Processing and Metrics

According to the FDA's website, FOIA requests 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 is assigned to a division within the FDA Center that regulates vaccines and other biological products for human use, the Center for Biologics Evaluation and Research ("CBER").[32]

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), which are reported for

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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.

the agency as a whole, rather than for individual Centers such as CBER.[33] Agency-wide FOIA metrics for the FDA from 2014 to 2022 (presented below in Table 1), 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 amount spend by the FDA on processing FOIA requests within the agency has gone down dramatically 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.

TABLE 1: FDA AGENCY-WIDE FOIA METRICS 2014-2022[34]

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

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

[34] The metrics in the Table 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.

B. FOIA Processing and Metrics Within CBER

As noted above, FOIA requests for vaccine-related information are assigned to the FDA Center that regulates vaccines, CBER. Within CBER, FOIA requests go to CBER's Division of Disclosure and Oversight Management ("DDOM"), where they are processed by the Access Litigation and Freedom of Information Branch ("ALFOI").[35] ALFOI places each request in one or more of ALFOI's six processing queues, based on the volume, complexity, and/or subject matter of the requested records. ECF 11-2, ¶ 12. The "complex" queue, to which CHD's request was assigned, contains requests that require "extensive time to locate, review, and/or redact the records and often involve voluminous records." *See CHD v. FDA*, Case 1:23-cv-00220-RDM, ECF 20-1, Supplemental Declaration of Suzann Burk, ¶ 4.

ALFOI's FOIA workload from Fiscal Years 2015-2022 is summarized in the Declaration of Suzann Burk. See ECF 11-2 ¶¶ 18-21. Of note, at the end of FY 2022, ALFOI had a backlog of 532 requests. *Id*. Within that backlog, at least 370 requests were in the "complex processing queue"—that is, the complex processing queue contained at least 70% of the total backlog for all six ALFOI queues, and 9% of the FDA's entire FOIA backlog. *See CHD v. FDA*, Case 1:23-cv-00220-RDM, ECF 20-1, Supplemental Declaration of Suzann Burk, ¶ 11.[36]

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

[36] The Supplemental Declaration indicates that as of October 18, 2023, a FOIA request CHD filed in July 2022 was in ALFOI's complex queue behind 368 earlier-submitted FOIA requests, which means that at the end of FY 2022, including the July 2022 plus the request in the instant case, at *least* 370 of ALFOI's backlogged requests were in the complex queue. This number understates the FY 2022 complex queue backlog by however many backlogged complex requests the FDA processed between the end of FY 2022 and October 18, 2023.

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," AND BECAUSE THE REQUESTED RELIEF IS NOT AUTHORIZED BY THE FOIA.

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),[37] 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 at 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.

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[37] *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.

§ 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] 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—*i.e.*, if a defendant agency shows both "due diligence" and "exceptional circumstances"—a court "may retain jurisdiction and allow the agency additional time to complete its review of the records." 5 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 vaccine-related records to ALFOI, the *responsibility* for processing those requests in compliance with the FOIA remains with the FDA itself; this responsibility includes timely processing of requests in ALFOI's complex processing queue.

B. The FDA Has Not Shown and Cannot Show 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, despite the FDA's suggestions to the contrary, the FOIA requires the agency to show due diligence in responding to the *plaintiff's* request, rather than merely by 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 and 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").

The FDA's "due diligence" argument and supporting declaration is bereft of any argument with respect to CHD's request. Instead, the FDA discusses the many steps ALFOI has

taken to process FOIA requests *in general* and for *other* requesters. *See* ECF 11-1, Memorandum in Support of Defendant's Motion for an Eighteen-Month Stay of Proceedings, at 15-17 (discussing ALFOI's general FOIA-processing efforts and processing of records in other FOIA litigation); ECF 11-2, Declaration of Suzann Burk, at ¶¶ 7–8, 12-17 and 22-30 (discussing ALFOI's general FOIA-processing efforts as well as efforts in connection with processing requests from the Siri & Glimstad law firm that have nothing to do with the instant case). By contrast, with respect to CHD's request *in particular*, the FDA admits only that it has not taken *any* steps to process the request. *See* ECF 11-1 at 15-16. Further, the FDA's declaration in support of its motion to stay does not provide a satisfactory explanation as to why the agency asks this court to put CHD's FOIA request on hold for at least another year and a half while it continues to process other FOIA requests filed after the agency received CHD's request in September 2022.

The FDA claims in passing that its current hiring and training efforts demonstrate "due diligence" in addressing a backlog of FOIA requests that includes CHD's request. ECF 11-1 at p. 16. However, as shown in the FOIA metrics presented above, while the annual number of FOIA requests received by the agency has gone down since 2019, the agency's FOIA backlog has *grown* since then. And notably, the backlog increased in 2021, *before* the *PHMPT 1* production order.

As discussed above, within ALFOI, it appears that as of the end of 2022, the "complex processing queue" (to which CHD's request was assigned at some point before May 2023) had a greater request backlog than the total, combined backlog in ALFOI's five other queues, constituting nearly one tenth of the FDA's total FOIA backlog. However, the FDA's declaration omits any information about how the agency is working to address the request backlog in the

complex processing queue. *See* ECF 4, ¶ 17. The declaration does not address the question of how many individuals within ALFOI's limited workforce the FDA has dedicated to processing the backlog, but the answer appears to be straightforward: not enough. Indeed, given the 24-plus-month wait before requests in the complex queue are even assigned for processing, "processing queue" is a misnomer; "locked in cold storage" more aptly describes the status of ALFOI's complex requests. The fact that ALFOI assigns incoming request to one of six processing queues does not show due diligence, where one of the queues is virtually at a standstill.

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. For this reason alone, the Agency is not entitled to an *Open America* stay.

C. The FDA Has Not Shown and Cannot Show Exceptional Circumstances

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*.; *see also Daily Caller News Found. v. FBI*, 387 F. Supp. 3d 112, 116 (D.C. Cir. 2019).

1. The FDA has Not Shown and Cannot Show That It Faces an Unforeseen and Remarkable Number of Requests

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."

Nonetheless, 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 *ALFOI* lacks the "bandwidth" to fulfill CHD's request. *See* ECF 11-1 at 12-14; ECF 11-2 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 obtained and 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 March 13, 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 obtain and allocate sufficient resources to and within ALFOI to keep up with ALFOI's increasing, complex FOIA workload.

The production burden ALFOI faces in the *PHMPT Litigation* also is not a surprise, because in addition to FOIA's 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 need to be made 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 complex 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,[38] 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.[39] 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,

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[38] 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.

[39] 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/.

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[40] and the Pfizer shot for children,[41] 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 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*, the FDA suggests that ALFOI's involvement in other FOIA lawsuits contribute to ALFOI's inability to process CHD's request. *See* ECF 11-1 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.

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[40] *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.

[41] *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.

2. The FDA has Not Shown and Cannot Show that it Lacks the Resources to Meet its Current FOIA Obligations, Including its Obligations to CHD

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. But the FDA does not claim that it lacks the resources to meet its overall transparency obligations. And indeed, the agency's resources are plentiful: in fiscal year 2023, the agency 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. Moreover, 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.

While the substantial production requirements under *PHMPT 2* pose a challenge for the relatively small number of FDA FOIA personnel within ALFOI, it is important to remember the size of the FDA's overall budget and workforce.[42] Thus, if the current ALFOI workforce needs assistance, the FDA certainly has the resources to provide that help. Indeed, the FDA has been through several budget cycles since the first PHMPT FOIA request was filed, for records that the FDA knew it would have to disclose, and thus the FDA has had ample opportunity to budget and allocate resources appropriately.

[42] *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.

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.[43] *See* ECF 11-2, Declaration of Suzanne Burk, at ¶ 18. Notably, 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 ¶ 23. Meanwhile, in the Spring of 2023, CBER also hired six additional full-time FOIA employees.[44] *Id*. at ¶ 25. Thus, an equivalent of 25.5 full-time staff now work on FOIA requests within ALFOI.

As discussed above, it appears that within ALFOI, the "complex" processing queue presents the heaviest workload, given the nature of the queue and the huge backlog in that queue compared with the other five queues. The FDA's declaration does not indicate how many employees are assigned to work on requests from the complex processing queue, but based on the backlog and the length of time a request languishes in the queue before it is assigned for processing, it is clear that even within ALFOI, FDA needs to reallocate resources so as to better meet its transparency obligations. The term "processing queue" is misleading at best; as noted above, the complex queue is nothing more than cold storage.

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

[44] 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.

FDA does not claim that it lacks the resources to process CHD's request in particular. The Burke declaration describes the FDA's legal obligations to protect exempt information when processing *any* FOIA request (*see* ECF 11-2, ¶¶ 9-11), and enumerates the steps ALFOI must take when processing *any* FOIA request (see *id.*, ¶¶ 12-17). And the FDA's memorandum makes it clear that the "additional work" it must do to process CHD's request is not "additional" at all but rather is identical to the work that *any* agency must do to process *any* FOIA request, to wit: "develop search terms, identify record custodians, and conduct a search for potentially responsive records," then "review the records to determine whether they are responsive to Plaintiff's FOIA request," and if so, then "conduct a line-by-line review of each responsive record to determine whether any information therein is exempt from disclosure under the FOIA." *See* ECF 11-1, p. 8.

In a section entitled "Sensitivity of the Records," the FDA notes that CHD's request "appears to seek, among other things, records related to adverse events of special interest following COVID-19 vaccination,"[45] and that the agency "must take the time and have the resources necessary to carefully process potentially responsive records and determine whether any FOIA exemptions apply." *See id.*, p. 19. In other words, according to the FDA, the agency will be required to use resources to process CHD's FOIA request exactly as *any* agency must use resources to process *any* FOIA request it receives.

FDA further notes that when processing CHD's request, it "may need to determine whether information in the potentially responsive records is pre-decisional and deliberative. FDA may also need to review to protect privacy interests discussed in the records. Furthermore, FDA

[45] It is true that the request seeks records that "relate to" AESIs, but it's important to note that the records should include solely or primarily aggregate and statistical data rather than personal medical information. *See, e.g., Protocol*, pp. 12-13, an "Example table of descriptive statistics."

may need to protect proprietary information under Exemption 4, which provides "private parties with sufficient assurances about the treatment of their proprietary information so they will cooperate in federal programs and supply the government with information vital to its work." *Id*., pp. 19-20. Again, there is nothing to see here; FDA is obligated to process CHD in light of FOIA exemptions, just as *any* agency is obligated to process *any* FOIA request in light of those exemptions.

Citing *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. __, 139 S. Ct. 2356, 2366 (2019), the FDA notes that both the agency and this Court have responsibilities to "patients and proprietary-information holders," and that "[a] group of FOIA requestors, through the collective burden of their voluminous requests that could overwhelm an agency's FOIA processing capabilities, should not be able to subvert the FOIA exemptions' 'important interests.'" ECF 11-1, p. 20. CHD agrees, and so did Congress; that is why it enacted 5 U.S.C. § 552(a)(6)(C)(i), which allows a court to modify FOIA time limits *when the legal standard is met*, that is, when the agency can show both "due diligence" and "exceptional circumstances." But here, as discussed above, FDA fails to meet the legal standard.

Here, the FDA's current obligations under FOIA were wholly foreseeable, and the agency 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, and—apparently—an even more miniscule portion to the complex processing queue, does not entitle the FDA to ignore the FOIA'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 allocate resources in a way that allows it to fully meet those obligations. In the meantime, where FDA has failed to show "exceptional circumstances," *Open America* does not give the agency license to shift the cost of its mistakes to CHD.

D. The Relief Sought by FDA is Not Authorized by 5 U.S.C. § 552(a)(6)(C).

Even if the FDA showed "due diligence" and "exceptional circumstances"—which it has not—the relief sought by FDA is not authorized by the FOIA statute. When a defendant agency can show both "due diligence" and "exceptional circumstances," the FOIA allows a court to give the agency "additional time to *complete its review of the records*." See U.S.C. § 552(a)(6)(C) (emphasis added). Here, the FDA is not seeking time to *complete* any review of records; indeed, there are no records to review, because FDA has not even begun to search for potentially responsive records. Rather, the FDA is asking this court to *suspend all of its FOIA obligations* to CHD for a minimum of eighteen months.

The FDA's requested relief—an unconditional suspension of *all* FOIA obligations for *at least* eighteen months—far exceeds the relief provided in any of the cases the FDA cites to support its Motion to Stay, all of which required both production of records and ongoing oversight by the court. *See Energy Future Coal v. Off. Of Mgmt. & Budget*, 200 F. Supp. 3d at 163 (ordering defendant to *continue* reviewing 500 documents per month and producing responsive documents until all responsive documents have been produced, and to file a status report within 60 days of court's order and a second status report within 90 days after that); *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d at 57, 63, (staying proceedings for just over one month, after which Defendant was required to produce responsive records, and

warning, "[u]pon expiration of the stay, the court will not accept from Defendant an extended schedule to search for and produce responsive records. Ten months have already passed since Plaintiff made its request, which it then narrowed. It would behoove Defendant to take the next six weeks to craft and execute a plan to expeditiously produce the requested records upon expiration of this stay."); *Appleton v. FDA*, 254 F. Supp. 2d at 11 (ordering parties to clarify scope of plaintiff's request and to submit joint status report outlining results and proposing deadline for completed production); *Elec. Frontier Found. v. DOJ*, 517 F. Supp. 2d at 113 (granting stay of proceedings for one year with possibility of extension, during which defendant was required to make interim releases to plaintiff every four weeks, and file status reports with the Court every 90 days).

As these cases illustrate, Defendant's requested stay goes far beyond the bounds of what is authorized by 5 U.S.C. § 552(a)(6)(C).

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 this 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 ECF 11-1, Defendant's Memorandum, at 11.

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 11-1, Defendant's Memorandum, pp. 18-19.

The claim that CHD has "not articulated" an urgency for the documents is demonstrably 100% false. However, by making such a claim, the FDA sidesteps the need for it to actually discuss the question of urgency. CHD's original FOIA letter included a detailed request for expedited processing, s*ee* ECF 1-1, Exhibits, pp. 8-12, discussing the public's urgent need to understand what safety signals the FDA has detected through its active monitoring; how those signals have been investigated; and how the FDA continues to conclude that COVID-19 injections are safe. *Id*. at 11-12.

Information about FDA's active investigation of 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 shots 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 a COVID-19 shot 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 information is important for scientists who can independently analyze raw data once the FDA makes it available. It is hard to 'follow the science' when it the science is hidden.

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. 12.

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 11-1 at 18-19. Certainly, the United States is not a nation whose citizens are only entitled to information that is culled, curated, and composed by the government. Moreover, the licensing records produced in *PHMPT 1* do not replicate the records sought by CHD, which include active post-authorization monitoring of large claims databases, and in-depth, ongoing statistical analysis of potential safety signals. Indeed, the active monitoring *Protocol* notes that "[p]otential safety outcome risks of COVID-19 vaccines may not be captured in clinical trials, particularly for rare outcomes . . . Post-market active monitoring and reporting of COVID-19 vaccine-related AESIs enables better capture of rare safety outcome risks . . ." *See Protocol*, p. 6. Similarly, while the two webpages FDA cites in its pleading discuss dosing and

other matters, these webpages also have nothing to do with the records of active safety-monitoring records sought by CHD. 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.

Moreover, even if CHD had not clearly articulated urgency and injury from further delay, FDA's claim that CHD will not be injured by the long stay it requests demonstrates 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.

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 11-1 at 6 ("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 11-1, Defendant's Memorandum in Support of Motion to Stay, p. 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. Nor has the FDA indicated that 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 thousands of FOIA requests pending with FDA.

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 11-1, Defendant's Memorandum, p. 19. But keeping this case lingering on the Court's docket for at least another year and a half—with no obligation for the FDA 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. Additionally, CHD requests that the Court order the FDA to immediately commence processing of CHD's request, and within 30 days of the order, to file a report stating volume of responsive records and proposing a schedule for timely production of those records.

Date: November 13, 2023

Respectfully submitted,

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