UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, 852 Franklin Ave. Suite 511 Franklin Lakes, NJ 07417 Plaintiff, v. FOOD AND DRUG ADMINISTRATION Defendant.	)	**Case No._____**

EXHIBITS TO COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

EXHIBIT 1

Children's Health Defense

September 7, 2022

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Access Litigation and Freedom of Information Branch
10903 New Hampshire Avenue
Building 71, Room 1114
Silver Spring, MD 20993-0002

Submitted via FDA's ONLINE FOIA PORTAL

Re: Freedom of Information Act Request for records of CBER's ongoing safety monitoring of COVID-19 vaccines through the BEST initiative

Dear Sir or Madam:

Children's Health Defense (CHD) is a non-profit made up of public health professionals, medical professionals, lawyers, scientists, and journalists. CHD's mission includes disseminating public health information and data, which CHD does through its publication, website, newsletter, press briefings, media channel, and social media platforms.

In this FOIA request, CHD seeks records connected with ongoing safety monitoring of COVID-19 vaccines. The Background for the request ends and the request for records begins on page 3.

Background

Since the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations for various COVID-19 vaccines in December 2020, the federal government has consistently touted COVID-19 vaccination as "safe and effective,"[1] and has engaged in ongoing efforts to ensure that all members of the U.S. population receive COVID-19 vaccines and boosters.

As part of its effort to ensure broad COVID-19 vaccine acceptance and uptake, the government has consistently assured the public that U.S. public health agencies are vigilantly monitoring the COVID-19 vaccine for safety. For example, on a web page

[1] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last accessed July 11, 2022).

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."[2]

On its "COVID-19 Vaccine Safety Surveillance" webpage, the FDA summarizes the COVID-19 vaccine safety monitoring efforts it is undertaking through the Center for Biologics Evaluation and Research (CBER).[3] Of relevance to this FOIA request, these efforts include ongoing surveillance through the Biologics Effectiveness and Safety System (BEST Initiative) to monitor about fifteen adverse events of special interest (AESIs).[4]

The goal of the BEST Initiative, as described in CBER's "COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol" (BEST Protocol) is to "monitor the rates of various adverse events of special interest (AESIs) following COVID-19 vaccination in near real-time following authorization or licensure."[5] The monitoring is intended 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."[6]

Notably, the BEST Protocol "is a method for signal detection and not signal evaluation" and promises that "[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."[7]

An Addendum to the BEST Protocol entitled "Background Rates of Adverse Events of Special Interest for COVID-19 Vaccine Safety Monitoring," (hereinafter "Background Rates Study") outlines the methods used by CBER to establish background rates of the AESIs in various populations over the period from 2017 to 2020 for use in "sequential active monitoring for the safety of COVID-19 vaccines."[8] The background rates are noted in a set of documents posted on the BEST initiative website.[9]

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[2] *See* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (emphasis added) (last accessed July 11, 2022); *see also* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (emphasis added) (last accessed July 11, 2022).

[3] *See* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (last accessed July 12, 2022).

[4] *Id*.

[5] *See* https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf at p. 6.

[6] *See id.*

[7] *See id.*.

[8] *See* https://bestinitiative.org/wp-content/uploads/2021/01/C19-Vaccine-Safety-AESI-Background-Rate-Protocol-2020.pdf at p. 7.

[9] https://bestinitiative.org/wp-content/uploads/2022/08/Background-Rates-of-Adverse-Events-of-Special-Interest_for_COVID-19_Vaccine_Safety_Monitoring-All_Files.zip (last accessed September 1, 2022).

Addenda to the BEST Protocol ("BEST Protocol Addenda") describe CBER's similar, ongoing, adverse event monitoring and analysis with respect to COVID-19 booster shots,[10] and COVID-19 vaccines for children.[11]

Requested Records

This FOIA request follows up on the FDA's assurances of safety monitoring by requesting information about the monitoring the FDA has done to date under the BEST initiative.

As used in this request, "records" includes data, summaries, charts, graphs, reports, slide decks, discussions, papers, presentations, internal communications such as emails and chat logs, conclusions, tables from all statistical runs, meeting recordings, and any other materials generated in connection with the listed subject, in whatever form the records exist.

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R Part 5, Children's Health Defense (CHD) requests the following records generated in connection with the BEST Protocol and the BEST Protocol Addenda[12] for each and every (a) data source studied,[13] (b) COVID-19 vaccine brand studied,[14] (c) age group studied, and (d) AESI studied[15]:

A) Descriptive summaries of observed rates of AESIs, described in section 4.5 on pages 12-13 of the BEST Protocol;
B) Records of the sequential analyses of AESIs described in section 4.6 on pages 13-24 of the BEST 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 BEST 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 BEST Protocol.

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[10] *See* 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).
[11] *See* 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); https://bestinitiative.org/wp-content/uploads/2022/04/C19-Active-Monitoring-Protocol-Addendum-2022.pdf (Addendum describing monitoring of AESIs among children under 18); (last visited July 11, 2022).
[12] https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf, https://bestinitiative.org/wp-content/uploads/2022/06/C19-Booster-Active-Monitoring-Protocol-Addendum-2022.pdf, https://bestinitiative.org/wp-content/uploads/2022/04/C19-Active-Monitoring-Protocol-Addendum-2022.pdf, https://bestinitiative.org/wp-content/uploads/2022/04/C19-Active-Monitoring-Protocol-Addendum-2022.pdf.
[13] A non-exhaustive list of potential data sources is included on pp. 7-8 of the Master Protocol. Please provide information for all data sources used, *whether or not* they appear on the Master Protocol list.
[14] The Protocol notes that the study objectives will be assessed for each COVID-19 vaccine brand. See https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf at p. 9.
[15] The Protocol specifies the AESIs studied on page 11, and describes the rationale for their selection on pages 10-11.

The records are requested for the period between February 1, 2021, and the date of response to this request.

Guidance Regarding the Search and Processing of Requested Records

In connection with its request for records, CHD provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations, FDA departments and systems likely to have responsive records, regardless of format, medium, or physical characteristics.

- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,[16] and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably searchable non-exempt portions of the requested records. Please also describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well and the reasons that statutory basis applies.

- If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.

- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

[16] Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

- Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeals and litigation. CHD reserves all rights to appeal the withholding or deletion of any information.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, CHD requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government—specifically, the taxpayer-funded FDA —and the disclosures are in the public interest, because they will likely contribute significantly to a better understanding of relevant government procedures by the general public.

The American public has a significant interest in having a full understanding of how the FDA and its agents are monitoring the safety of COVID-19 vaccines. The public's understanding of the government's activities would be enhanced through CHD's analysis and publication of these records.

In addition, this request is primarily and fundamentally for non-commercial purposes.[17] As a 501(c)(3) nonprofit, CHD does not have a commercial purpose and the release of the information requested is not in the organization's financial interest.

CHD works to end childhood health epidemics through efforts to expose causes, eliminate harmful exposures, hold those responsible accountable, seek justice for those injured, and establish safeguards to prevent future harm.

CHD uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. The organization also makes materials it gathers available on its public website[18] and newsletter and promotes their availability on social media platforms, such as Twitter.[19]

CHD has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous articles and analyses posted to its news website.[20]

Accordingly, CHD qualifies for a fee waiver. If CHD's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.

[17] *See* 5 U.S.C. § 552(a)(4)(A)(iii).
[18] *See* Children's Health Defense, https://childrenshealthdefense.org/.
[19] *See* https://twitter.com/ChildrensHD.
[20] *See* The Defender https://childrenshealthdefense.org/defender/.

Request for Expedited Processing

CHD requests expedited processing of this request, because there is a "compelling need." *See* 5 U.S.C. § 552(a)(6)(E)(i)(II). CHD is "primarily engaged in disseminating information," and there is "urgency to inform the public concerning actual or alleged Federal Government activity," namely, the FDA's ongoing, post-authorization COVID-19 vaccine pharmacovigilance activities. *See* § 552(a)(6)(E)(v)(II).

CHD is made up of public health professionals, medical professionals, lawyers, scientists, and journalists. CHD's mission includes disseminating public health information and data, which CHD does through its publication,[21] website,[22] newsletter, press briefings, media channel,[23] and social media platforms.[24]

CHD intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of CHD's individual members, including all its members who are journalists, are primarily engaged with disseminating information to the public and do so across various platforms including through interviews,[25] blogs,[26] articles,[27] essays,[28] podcasts[29] and videos.[30] Therefore, CHD and many of its members are "engaged in disseminating information to the general public."

Given the current, ongoing campaign for COVID-19 vaccination, the current, ongoing public concern about vaccine safety, and the current, ongoing public debate surrounding vaccine mandates and passports, there is an urgent public need for transparency with respect to the FDA's current, ongoing COVID-19 vaccine safety monitoring.

Since the FDA issued Emergency Use Authorizations for various COVID-19 vaccines in December 2020, the federal government has engaged in ongoing efforts to ensure that all members of the U.S. population receive COVID-19 vaccines and boosters. These efforts include purchasing billions of dollars of COVID-19 vaccines for distribution to the

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[21] *See* https://childrenshealthdefense.org/defender/
[22] *See* https://childrenshealthdefense.org/
[23] *See* CHD.TV https://live.childrenshealthdefense.org/
[24] *See* https://www.facebook.com/ChildrensHealthDefense, https://twitter.com/ChildrensHD, https://rumble.com/user/childrenshealthdefense.
[25] *See e.g.,* https://childrenshealthdefense.org/defender/chd-tv-rfk-jr-defender-vanden-bossche-vaccinating-omicron-pandemic/, https://childrenshealthdefense.org/defender/meryl-nass-tessa-lena-under-attack/, (last accessed March 7, 2022).
[26] *See* https://childrenshealthdefense.org/defender/
[27] *See e.g.,* https://childrenshealthdefense.org/defender/ivermectin-beats-meds-treating-omicron/
[28] *See e.g.,* https://childrenshealthdefense.org/defender/cory-zue-coming-clean-stand-against-covid-vaccines/
[29] *See* The Defender Podcast, Robert F. Kennedy, Jr., https://podcasts.apple.com/us/podcast/rfk-jr-the-defender-podcast/id1552000243
[30] *See* https://live.childrenshealthdefense.org/

general public[31]; providing funding for broad-based vaccine distribution efforts throughout the United States;[32] imposing nationwide COVID-19 vaccine mandates;[33] paying billions of dollars to media sources to provide positive coverage of COVID-19 vaccines;[34] and working with social media companies to ensure positive coverage of COVID-19 vaccines and censor alternative viewpoints.[35]

The federal government's push towards universal vaccination has been aided through mandates imposed by businesses, schools, and state and local governments, on students, employees, and customers.[36] And now that the FDA has authorized booster

[31] *See, e.g.*, https://www.hhs.gov/about/news/2022/06/29/biden-harris-administration-secures-105-million-doses-of-pfizers-latest-covid-19-vaccine-for-fall-vaccination-campaign.html (last accessed July 14, 2022).
[32] *See* https://www.cdc.gov/media/releases/2021/p0407-covid-19-vaccine-programs.html#:~:text=The%20Centers%20for%20Disease%20Control,virus%20that%20causes%20COVID%2D19 (last accessed July 11, 2022).
[33] *See* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/, https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/ (last accessed July 11, 2022).
[34] *See* https://www.congress.gov/bill/117th-congress/house-bill/1319/text; *see also*, https://www.hhs.gov/about/news/2021/04/01/hhs-launches-nationwide-network-trusted-voices-encourage-vaccination-next-phase-covid-19-public-education-campaign.html. According to the Department of Health and Human Services, "The [media campaign's] influencer strategy is to cultivate and collaborate with a range of influencers, including community leaders, celebrities, musicians, artists, entertainers, medical experts, and digital creators, to amplify Campaign messaging to target audiences. Our goal is to increase trust and confidence in the COVID vaccines with our key audiences by strategically leveraging an individual's influence with their followers." *See* https://wecandothis.hhs.gov/resource/campaign-approach-to-reaching-general-audiences#paid-media (last accessed July 11, 2022).
[35] *See* https://aaronkheriaty.substack.com/p/our-lawsuit-uncovers-army-of-federal?utm_source=brownstone&utm_medium=web; https://www.aflegal.org/news/afl-lawsuit-reveals-damning-cdc-documents-proving-government-collusion-with-big-tech-to-censor-free-speech-and-promote-biden-administration-propaganda; https://ftp.aflegal.org/foia/HHS/COVID%20Disinformation%20-%20CDC%20-%2021-01575-FOIA/286%20pages_Second%20Interim%20Release_22-00003-LT.pdf (last accessed August 23, 2022).
[36] *See, e.g.,* https://www.kff.org/report-section/state-covid-19-data-and-policy-actions-policy-actions/; https://www.bestcolleges.com/news/2021/10/11/list-of-colleges-that-require-covid-19-vaccine/#:~:text=A%20still%2Dexpanding%20group%20of,and%20public%2C%20have%20followed%20suit; https://www.nashp.org/states-enact-policies-to-support-students-transition-back-to-school/; https://news.bloomberglaw.com/daily-labor-report/vaccine-mandates-at-work-part-of-new-normal-employers-say; https://ny.eater.com/2022/3/9/22967384/nyc-restaurants-bars-proof-of-vaccination-requirement (last accessed July 14, 2022).

shots for children and adults,[37] along with COVID-19 vaccines for children as young as six months,[38] the push towards universal vaccination has only intensified.[39]

Although the federal government has consistently touted the vaccines as "safe and effective," the COVID-19 vaccine clinical trials were not large enough or long enough to determine overall safety profile of the vaccines. Additionally, they did not study the vaccines' safety in uniquely vulnerable sub-populations, such as pregnant women. Thus, federal public health agencies' ongoing post-authorization COVID-19 vaccine safety monitoring is crucial to understanding the full risks associated with the vaccines.[40] And the FDA, among other agencies, has consistently assured the public that it is vigilantly monitoring the COVID-19 vaccine for safety.[41]

Despite the assurances by U.S. public health agencies that the vaccines are "safe and effective," numerous scientists, physicians, public health experts, and vaccine-injured individuals have questioned the vaccines' safety,[42] and there has been ongoing public

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[37] *See* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and#:~:text=The%20agency%20amended%20the%20emergency,or%20approved%20COVID%2D19%20vaccine.; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-booster-dose-16-and-17 (last accessed July 14, 2022).

[38] *See* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children#:~:text=For%20the%20Pfizer%2DBioNTech%20COVID,years%20of%20age%20and%20older (last accessed July 14, 2022).

[39] *See, e.g.,* https://www.whitehouse.gov/briefing-room/press-briefings/2022/07/12/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-87/; https://www.newsweek.com/why-america-doesnt-trust-cdc-opinion-1713145; https://www.cdc.gov/about/leadership/director-debriefing.html; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?s_cid=11368:5%20year%20old%20covid%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21 (last accessed July 14, 2022). Indeed, the CDC recommends that eligible, non-immunocompromised individuals stay "up to date with COVID-19 vaccines" including boosters. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fbooster-shot.html (last accessed September 1, 2022).

[40] As noted in CBER's December 2021 BEST Initiative "*Background Rates of Adverse Events of Special Interest for COVID-19 Vaccine Safety Monitoring*," "As with all licensed or authorized vaccines, there can be limitations in the safety data accrued from the pre-licensure or pre-authorization COVID-19 vaccine clinical studies. Clinical trials may not adequately represent special populations, such as pregnant women, and may not be large enough to capture all potential safety risks, particularly for rare health events. Post-market surveillance of potential adverse events of special interest (AESI) following vaccination is needed to continue monitoring the safety of approved or authorized COVID-19 vaccines." *See* https://bestinitiative.org/wp-content/uploads/2022/08/Background-Rates-of-Adverse-Events-of-Special-Interest_for_COVID-19_Vaccine_Safety_Monitoring-All_Files.zip.

[41] *See* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (emphasis added) (last accessed July 11, 2022); *see also* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (emphasis added) (last accessed July 11, 2022).

[42] *See, e.g.,* https://www.sciencedirect.com/science/article/pii/S0264410X22010283?utm_source=substack&utm_medi

weighing of the risks and benefits of the vaccines,[43] and ongoing public debate about public health policy, including the wisdom, legality, and morality of COVID-19 vaccine mandates and passports.[44]

The public includes private individuals who are faced with immediate decisions about whether to take COVID-19 vaccines and boosters, whether to vaccinate their children, and whether to politically support vaccine mandates and passports. The public also includes scientists, medical professionals, and policymakers faced with immediate decisions about how to advise and treat patients and constituents.

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

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um=email; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239#; https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf; https://rwmalonemd.substack.com/p/sars-cov2-spike-protein-is-a-toxin; https://childrenshealthdefense.org/defender/covid-vaccine-spike-protein-travels-from-injection-site-organ-damage/; https://www.wsj.com/articles/fda-shuts-out-its-own-experts-in-authorizing-another-booster-covid-vaccine-pandemic-science-11649016728; https://childrenshealthdefense.org/defender/joe-rogan-robert-malone-interview-covid-vaccine/; https://covid19criticalcare.com/; https://jessicar.substack.com/p/dose-3-response-much-like-sore-thumb?utm_source=substack&utm_medium=email https://worldcouncilforhealth.org/multimedia/ga-47?utm_source=substack&utm_medium=email; https://jessicar.substack.com/p/theres-been-a-44-increase-in-death; https://jessicar.substack.com/p/is-covid-19-injection-induced-myocarditis; https://rwmalonemd.substack.com/p/letter-to-the-uk-gov-from-76-doctors; https://thehighwire.com/videos/live-in-d-c-expert-panel-on-medical-mandates-vaccine-injuries/; https://pubmed.ncbi.nlm.nih.gov/35723296/; https://twitter.com/P_McCulloughMD/status/1545464447027888130 (last accessed July 14, 2022).

[43] An article published on August 31, 2022 in the journal *Vaccine*, using a simple harm-benefit comparison from clinical trial data, finds that the "excess risk of serious AESIs to exceed the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials," and urges additional, deeper risk-benefit analysis. *See "Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults*," Fraiman, et al., Discussion section. https://www.sciencedirect.com/science/article/pii/S0264410X22010283?via%3Dihub. And the CDC's own recently-released data indicates protection offered by the vaccine against Omicron is less than against previous strains, and wanes rapidly, raising further concerns about the vaccines' risk-benefit ratios. *See* https://www.theepochtimes.com/covid-19-vaccine-effectiveness-plunges-against-omicron-cdc-data_4704255.html?utm_source=Health&utm_campaign=health-2022-09-02&utm_medium=email&est=5Bj%2BStK%2ByB58GCQxlqAuDxrLn%2BkgOXPplHT5zlBIJcGZ816tVG2pqzzU13Q%3D; https://www.documentcloud.org/documents/22273715-cdc-slides-sept-1;

[44] See, e.g., https://www.nashp.org/state-lawmakers-submit-bills-to-ban-employer-vaccine-mandates/; https://www.latimes.com/california/story/2022-04-10/hundreds-gather-for-defeat-the-mandates-rally-in-downtown-l-a. Evidence of the magnitude of the debate is found, among other places, in the numerous lawsuits that have been brought to challenge COVID-19 vaccine mandates. *See, e.g.*,*Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661 (2022) (challenging OSHA COVID-19 vaccine mandate); *Biden v. Missouri*, 142 S. Ct. 647 (2022) (challenging healthcare worker mandate); *Pavlock, et al, v. Jay A. Perlman, M.D., Bd. of Regents for the Univ. Sys. of Maryland, et al*, No. CV RDB-21-2376 (D. Md. Sept. 1, 2022) (challenging university's COVID-19 vaccine mandate); *Lukaszczyk v. Cook Cnty.*, No. 21-3200 (7th Cir. Aug. 29, 2022) (challenging state and local COVID-19 vaccine mandates)

need to understand how the FDA continues to reach its conclusion that the COVID-19 vaccines are safe.

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.

Because there is compelling need, expedited processing of this request is warranted, and FDA should produce the data and information necessary to address this critically important public issue by immediately producing the records sought in this FOIA request.

CHD certifies that the foregoing statements regarding the basis for expedited processing are true and correct to the best of our knowledge and belief. 5 U.S.C. § 552(a)(6)(E)(vi).

Conclusion

CHD and the FDA share a common mission to promote public health and transparency in government. By working together at the outset, we can decrease the likelihood of costly and time-consuming litigation in the future. If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of the records, please do not hesitate to contact CHD to discuss this request.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to Children's Health Defense at 852 Franklin Ave., Suite 511, Franklin Lakes, New Jersey, 07417. If it will accelerate the release of responsive records to CHD, please provide responsive material on a rolling basis.

You can reach me at [redacted] or [redacted]

Thank you for your time and attention to this matter.

Sincerely yours,

Risa Evans, Senior Legal Fellow, for
Children's Health Defense

EXHIBIT 2

U.S. FOOD & DRUG ADMINISTRATION

August 02, 2022

CHILDREN'S HEALTH DEFENSE
RISA EVANS
852 Franklin Ave., Suite 511
Franklin Lakes NJ 07417 US

In Reply refer to
FOIA Control #:
2022-5587

Requester reference:

Dear Requester:

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

Records of the daily email alerts/Daily Priority Reports received by FDA and/or CBER from CDC's VAERS contractor, including but not limited to any lists of VAERS ID numbers for reports of adverse events of special interest (AESIs) after COVID-19 vaccines;10 2) Records of any manual review of serious ASEI reports conducted by FDA and/or CBER etc

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

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

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

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

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

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

and/or

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

Sincerely,

SARAH KOTLER
Director

EXHIBIT 3

U.S. FOOD & DRUG ADMINISTRATION

September 14, 2022

CHILDREN'S HEALTH DEFENSE
CHILDREN'S HEALTH DEFENSE
852 Franklin Ave. Suite 511
Franklin Lakes NJ 07414 US

In Reply refer to
FOIA Control #:
2022-6494

Requester reference:

Dear Requester:

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

Descriptive summaries of observed rates of AESIs, described in section 4.5 on pages 12-13 of the BEST Protocol; B) Records of the sequential analyses of AESIs described in section 4.6 on pages 13-24 of the BEST Protocol (including both PMaxSPRT and BMaxSPRT); etc

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

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

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

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

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

Sincerely,

SARAH KOTLER
Director

EXHIBIT 4

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA 2022-6494

CHD FOIA <foia@childrenshealthdefense.org> Wed, Oct 12, 2022 at 4:46 PM
To: beth.brocknerryan@fda.hhs.gov

Hello,

I'm writing in connection with FOIA 2022-6494, which was filed on September 7, 2022. Would FDA please provide us with a final determination on the request, or else provide a date by which we can expect such determination?

Thank you!
Sincerely,
Risa Evans, for
Children's Health Defense

PS Please note that the original FOIA was filed from my personal gmail address during a time when FDA was not accepting emails from Children's Health Defense. That problem has been solved, so we would like to switch correspondence about FOIA 2022-6494 to this CHD FOIA email address.

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA 2022-6494

CHD FOIA <foia@childrenshealthdefense.org> Fri, Nov 18, 2022 at 4:57 PM
To: beth.brocknerryan@fda.hhs.gov

Hello,
I'm writing to follow up on my email of October 12, 2022, requesting a final determination on FOIA 2022-6494, or a date by which we can expect such determination.
Thank you for any information.
Sincerely,
Risa Evans, for
CHD
[Quoted text hidden]

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

Status of pending FOIA requests

CHD FOIA <foia@childrenshealthdefense.org> Tue, May 16, 2023 at 1:39 PM
To: elizabeth.sly@fda.hhs.gov
Bcc: CHD FOIA <foia@childrenshealthdefense.org>

Hi Ms. Sly,

Thank you for the phone call on May 11, 2023. I'm writing to confirm my understanding about the status of the various requests we discussed, and also to ask about the status of a request that we did not yet discuss.

Here's a recap of the requests we discussed. Please let me know if any aspect of my understanding is incorrect:

- **#2022-6494**: This request is clear as written, and FDA does not need any further clarification. This request has been assigned to the "complex" track for processing. There are hundreds of requests ahead of #2022-6494 in the complex track. Accordingly, this request will not be assigned for processing for at least 24 months.
- **#2022-7832**. With the clarification provided in my narrowing email sent to Sarah Kotler on November 2, 2022, this request is clear and FDA does not require further clarification. This request has been assigned to the "complex" track for processing. There are hundreds of requests ahead of #2022-7832 in the complex track. Accordingly, this request will not be assigned for processing for at least 24 months. However, there are related requests ahead of #2022-7832, and when those requests are fulfilled, FDA will do a "fill from" with any responsive records from those earlier requests. After doing the "fill from," if necessary to complete the request, FDA will process our request according to the 24-month timeline described above.
- **#2022-7928:** This request is clear as written, and FDA does not need any further clarification. This request has been assigned to the complex processing queue. There are hundreds of requests ahead of #2022-7928 in the complex track, and this request will not be assigned for processing for at least 24 months. However, FDA possesses previously-released materials relating to the requested subject matter, and will provide those in partial fulfillment of the request. If items on the request remain after these materials are provided, FDA will process the request according to the 24-month timeline described above.
- **#2023-294**: This request is clear as written, and FDA does not need any further clarification. This request has been assigned to the "complex" track for processing. There are hundreds of requests ahead of #2022-6494 in the complex track. Accordingly, this request will not be assigned for processing for at least 24 months.
- **#2023-349**: This request has been assigned to the Office of Acquisition Services for processing.

As for requests that we did not discuss, I wanted to check on the status of **#2023-2075,** which was filed on March 14, 2023. Two questions about this request; if a phone call would be preferable to email, please let me know and we can schedule a call.

- First, we did not receive any indication that the request is unclear or overbroad. Can you confirm that FDA does not require any clarification from us before processing request #2023-2075 ?
- Second, the request for expedited processing was denied. Based on our recent conversation, I would anticipate that this request has been assigned to the complex track, and will not be assigned for processing for at least 24 months. Is this correct?

Thank you again for your time and the info you provided, and in advance for your responses to these additional questions.
Best,
Risa Evans, for
Children's Health Defense