UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, 852 Franklin Ave. Suite 511 Franklin Lakes, NJ 07417 Plaintiff, v. CENTERS FOR DISEASE CONTROL AND PREVENTION, Defendant.	)	**Case No._____**

EXHIBITS TO COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 16, 2022

Divyanshi Dwivedi
Children's Health Defense
Via email: divyanshi.dwivedi@childrenshealthdefense.org

Dear Ms. Dwivedi:

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of May 9, 2022, assigned #22-01479-FOIA (copy attached).

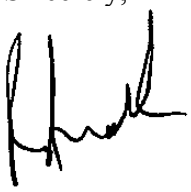
We located 104 pages of responsive records for Item 1 of your request. After a careful review of these pages, no information was withheld from release.

In regards to Item 2, program staff within the Immunization and Safety Office inform me that no PRRs were conducted by CDC. Furthermore, data mining is outside of th agency's purview; staff suggest you inquire with FDA.

In regards to Item 3, program staff inform me that, while VAERS has conducted "signal assessment" as described in section 2.5 (i.e. assessed that a causal association exists between the vaccine and both TTS and myocarditis), that assessment involved no formal records. Documentation for this exists in ACIP presentations and publications in the biomedical literature. For your convenience, a listing of those publications is included.

If you need any further assistance or would like to discuss any aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6246.

Sincerely,



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

22-01479-FOIA

EXHIBIT 2

Children's Health Defense

August 23, 2022

VIA CDC'S ONLINE FOIA PUBLIC ACCESS LINK
CDC FOIA Office

Re: Freedom of Information Act Request for records in connection with CDC's efforts to detect COVID-19 vaccine safety signals in VAERS through Proportional Reporting Ratio data mining and follow-up

To Whom it May Concern:

I. INTRODUCTION & OVERVIEW

The Centers for Disease Control and Prevention's (CDC) January 2021 "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)" (VAERS SOP) describes the CDC's plans to monitor VAERS for COVID-19 vaccine safety signals, and to follow up on any potential signals. The VAERS SOP promises that in order to detect safety signals, the CDC will—among other things—conduct Proportional Reporting Ratio (PRR) data mining on a weekly basis.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Children's Health Defense (CHD) seeks records of any PRR conducted by the CDC in connection with COVID-19 vaccines from October 1, 2021, to the present, and any follow up done as a result of safety signals detected through the PRR. Additionally, CHD seeks records that will illuminate why the CDC chose to begin conducting PRR at the end of March 2022 instead of in February 2021, and why the CDC chose to conduct the PRR for a limited period of time, instead of on the ongoing basis described in the VAERS SOP.

These records are sought on an expedited basis. Below is the background for the request. The full request begins on page 5.

II. BACKGROUND

A) The CDC's obligations to conduct PRR for the purpose of identifying COVID-19 vaccine safety signals in VAERS

Since December 2020, as the federal government has pushed for almost all members of the U.S. population to receive COVID-19 vaccines and boosters, the government has touted COVID-19 vaccination as "safe and effective," and has indicated that it is engaging in ongoing efforts to ensure the vaccines' safety.[1] For example, on a webpage entitled "Safety of COVID-19 Vaccines," the CDC proclaims:[2]

> What You Need to Know
>
> - COVID-19 vaccines are **safe and effective**.
> - Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in US history.
> - CDC recommends COVID-19 vaccines for everyone 6 months and older and boosters for everyone 5 years and older, if eligible.

A crucial part of the CDC's COVID-19 vaccine safety monitoring is through the Vaccine Adverse Events Reporting System (VAERS). As described by the CDC, VAERS is the nation's "early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration."[3] Although VAERS cannot prove that a particular adverse event is caused by a particular vaccine, it "can give CDC and FDA important information. If it looks as though a vaccine might be causing a problem, FDA and CDC will investigate further and take action if needed."[4]

The CDC's January 2021 "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)" (VAERS SOP) indicates that the CDC and FDA are to perform "routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines."[5] The VAERS SOP describes in detail the safety monitoring methods to be used, including the use of data mining to

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[1] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last accessed August 23, 2022); https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance (last accessed August 17, 2022).
[2] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html?s_cid=10507:covid%20vaccine%20safety:sem.ga:p:RG:GM:gen:PTN:FY21 (last accessed August 17, 2022).
[3] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last accessed August 17, 2022).
[4] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last accessed August 17, 2022).
[5] *See* VAERS SOP at p. 3.

detect safety signals that indicate the need for further, clinical investigation. As of August 19, 2022, the VAERS SOP was still posted on the CDC's website, in unmodified form.

Of greatest significance to this FOIA request, the VAERS SOP states, "[t]wo main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means. Both have published literature suggesting criteria for detecting "signals." PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA."[6]

Under the VAERS SOP, the CDC is obligated to look for safety signals by performing PRR data mining on a weekly basis or as needed to identify adverse events (AEs) that are disproportionately reported relative to other AEs.[7]

Additionally, CDC is obligated to monitor the pattern or trend of PRR and data mining results to help determine when to initiate a clinical review.[8] When such clinical review is indicated for an Adverse Event of Special Interest (AESI), the CDC is obligated to review data including reports and medical records, time from vaccination to symptom onset, patient history and course of illness, and more.[9]

The VAERS SOP requires CDC to hold weekly VAERS Team COVID-19 meetings to analyze and interpret VAERS data and discuss signals or potential events of concern,[10] and to provide monthly summary of this data review to pertinent stakeholders, such as Immunization Safety Office (ISO) leadership and FDA partners.[11]

The VAERS SOP also requires CDC to collaborate with the Food and Drug Administration (FDA). Specifically, CDC must share and discuss the results of data mining analyses and signals with the FDA (which under the VAERS SOP, detects signals through regular empirical Bayesian data mining)[12] through weekly vaccine safety coordination meetings among ISO team members and FDA.[13]

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[6] VAERS SOP at 16 (citations omitted); see https://www.sciencedirect.com/science/article/pii/S0264410X15009822?via%3Dihub, at 4401, describing how disproportionality analysis such as PRR is used to detect safety signals.
[7] VAERS SOP at 11, 14, 16.
[8] VAERS SOP at 18.
[9] VAERS SOP at 11,
[10] VAERS SOP at 19.
[11] VAERS SOP at 18.
[12] VAERS SOP at 16-17.
[13] VAERS SOP at 11, 19.

b) CDC's conflicting statements to CHD and the Epoch Times regarding its use of PRR to detect COVID-19 vaccine safety signals in VAERS

On May 4, 2022, CHD filed a FOIA request with CDC in connection with the VAERS SOP, assigned #22-01479-FOIA. In relevant part, the request states:

> In accordance with "Standard Operating Procedures" (SOP) document updated Jan 29, 2021: https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf please disclose:
> . . .
>
> **2.** Copies of all tables, analyses and reports generated in connection with the "Signal Detection Analyses" described under sections 2.3 of the SOP document (including PRR's described in 2.3.1; Bayesian data mining described in 2.3.2; crude reporting ratios described in 2.3.3) from February 1, 2021, through Sept. 30, 2021, inclusive.

A June 16, 2022 final response letter for #22-01479-FOIA from CDC/ATSDR FOIA Officer Roger Andoh states in relevant part, "program staff within the Immunization and Safety Office inform me that no PRRs were conducted by CDC. Furthermore, data mining is outside of th[sic] agency's purview; staff suggest you inquire with FDA."

On July 23, 2022, the Epoch Times published an article by Zachary Stieber in connection with #22-01479-FOIA, quoting Dr. John Su of the CDC's Immunization Safety Office, the head of the CDC's VAERS team.[14] When asked for comment about the CDC's apparent failure to conduct PRR, Dr. Su told the Epoch Times in an email, "CDC has been performing PRRs since Feb 2021, and continues to do so to date."[15]

On August 11, 2022, the Epoch Times published another article by Mr. Stieber in connection with the CDC's monitoring of VAERS.[16] According to the article, a CDC spokeswoman told the Epoch Times that the CDC had "revisited several FOIA requests and as a result of its review CDC is issuing corrections."[17]

According to the spokeswoman, CDC started performing PRRs on March 25, 2022, and stopped performing PRRs on July 31, 2022.[18] The spokeswoman also indicated "PRR results were generally consistent with EB [Empirican Bayesian] data mining, revealing

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[14] https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html.
[15] *Id*.
[16] https://www.theepochtimes.com/exclusive-cdc-admits-it-gave-false-information-about-covid-19-vaccine-surveillance_4657836.html.
[17] *See id.*
[18] *Id*.

no additional unexpected safety signals. Given it is a more robust data mining technique, CDC will continue relying upon EB data mining at this time."[19]

III. REQUEST FOR RECORDS

As used in this request, "records" means data, summaries, charts, graphs, reports, discussions, papers, presentations, email communications, texts, conclusions, and any and all other materials generated in connection with the listed subject, in whatever form the records exist.

As used in this request, "CDC," means the entity as a whole, as well as any officer, official, employee, spokesperson, or agent, including but not limited to Roger Andoh and Dr. John Su, and any subordinate division or entity, including but not limited to the Immunization Safety Office (ISO) and the VAERS Monitoring Team.

As used in this request, "FDA" means the entity as a whole, as well as any officer, official, employee, spokesperson, or agent, and any subordinate division or entity, including but not limited to the Center for Biologics Evaluation & Research (CBER).

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA") and the implementing regulations of your agency, 45 C.F.R Part 5, CHD, a non-governmental organization, requests the following records in connection with the activities described in the VAERS SOP and in the CDC's subsequent statements about PRRs and data mining.

1. Records of all PRR conducted by CDC in connection with COVID-19 vaccines from October 1, 2021, to the present;
2. Records of all communication about PRR results and all follow-up investigation done in connection with those results (whether clinical review or other investigation) from October 1, 2021, to the present, within CDC, and all communications about these matters between CDC and FDA. This request includes but is not limited to records of the comparisons between PRR results and data mining results described by the CDC spokeswoman in her statement to the Epoch Times;
3. Records of all communications discussing, referencing, or mentioning Proportional Reporting Ratio, PRR (or PRRs), safety signal (or signals), signal detection, or data mining, from January 30, 2021, to the present, within CDC and between CDC and FDA, to the extent not already provided in response to numbers 1 and 2 above;

[19] *Id*.

4. Copies of or links to all papers, articles, presentations, or other scientific data that provided the basis for the CDC spokeswoman's Epoch Times statement that Empirical Bayesian data mining is a "more robust data mining technique" than PRR.

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, CDC 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,[20] 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

[20] 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.

basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

- 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.

IV. REQUEST FOR FEE WAIVER

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 CDC —and the disclosures are in the pulic 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 CDC and its agents are monitoring the safety of COVID-19 vaccines. CHD is committed to transparency and makes the responses agencies provide to FOIA requests publicly available. 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.[21] The mission of CHD is to work tirelessly to end childhood health epidemics by working to expose causes, eliminate harmful exposures, hold those responsible accountable, seek justice for those injured, and establish safeguards to prevent future harm. 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 uses the information gathered, and its analysis of it, to educate the public through reports, press releases, and other media. The organization makes materials it gathers available on its public website[22] and through its newsletter, and promotes the availability of these materials on social media platforms, such as Twitter.[23]

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, The Defender.[24]

Accordingly, CHD qualifies for a fee waiver.

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

V. REQUEST FOR EXPEDITED PROCESSING

CHD requests expedited processing of this request. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting the information is "primarily engaged in disseminating information, the urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling public need" for expedited processing. § 552(a)(6)(E)(v)(II).

CHD is an organization made up of public health professionals, medical professionals, lawyers, scientists, and journalists. CHD exists for the purpose of disseminating public health information and data and does so through its publication,[25] website,[26] newsletter, press briefings, media channel,[27] and social media platforms.[28]

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,[29] blogs,[30] articles,[31] essays,[32] podcasts[33] and videos.[34] Therefore, CHD and many of its members are "engaged in disseminating information to the general public."

There is a clear urgency and compelling need to inform the public concerning the CDC's activity in connection with 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 general public[35]; providing funding for broad-based vaccine distribution efforts

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[25] *See* https://childrenshealthdefense.org/defender/
[26] *See* https://childrenshealthdefense.org/
[27] *See* CHD.TV https://live.childrenshealthdefense.org/
[28] *See* https://www.facebook.com/ChildrensHealthDefense, https://twitter.com/ChildrensHD, https://rumble.com/user/childrenshealthdefense.
[29] *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).
[30] *See* https://childrenshealthdefense.org/defender/
[31] *See e.g.,* https://childrenshealthdefense.org/defender/ivermectin-beats-meds-treating-omicron/
[32] *See e.g.,* https://childrenshealthdefense.org/defender/cory-zue-coming-clean-stand-against-covid-vaccines/
[33] *See* The Defender Podcast, Robert F. Kennedy, Jr., https://podcasts.apple.com/us/podcast/rfk-jr-the-defender-podcast/id1552000243
[34] *See* https://live.childrenshealthdefense.org/
[35] *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).

throughout the United States;[36] imposing nationwide COVID-19 vaccine mandates;[37] paying billions of dollars to media sources to provide positive coverage of COVID-19 vaccines,[38] and working with social media companies to ensure positive coverage of COVID-19 vaccines and censor alternative viewpoints.[39]

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.[40] And now that the FDA has authorized booster shots for children and adults,[41] along with COVID-19 vaccines for children as young as six months,[42] the push towards universal vaccination has only intensified.[43]

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[36] *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 August 23, 2022).

[37] *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 August 23, 2022).

[38] *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 DHHS, "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 August 23, 2022).

[39] See 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).

[40] *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; (last August 23, 2022).

[41] *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).

[42] *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).

[43] *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-

During this push, numerous scientists, physicians, public health experts, and vaccine-injured individuals have questioned the safety of COVID vaccines.[44] Moreover, the COVID-19 vaccine clinical trials were not large enough or long enough to determine overall safety profile of the vaccines. Thus, federal public health agencies' ongoing COVID-19 vaccine safety monitoring is essential to understanding the full risks associated with the vaccines.

VAERS monitoring is currently a matter of tremendous public concern, as evidenced most recently by Sen. Ron Johnson's July 26 press release regarding the matter, coupled with his follow-up letter to CDC Director Rochelle Walensky.[45] The CDC's conflicting statements about whether and when it has conducted PRR, and its failure to follow the procedures promised in the VAERS SOP, heighten the concern about this issue.

Given the intensity of the ongoing campaign for universal COVID-19 vaccination in both the public and private sectors—including booster shots and vaccination of children and infants—there is an urgent public need for transparency with respect to the CDC's ongoing COVID-19 vaccine safety monitoring.

The public—made up of individuals who are faced with immediate decisions about whether to take COVID-19 vaccines and boosters, whether to vaccinate their children,

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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).

[44] *See, e.g.,* 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.theepochtimes.com/sars-cov-2-vaccines-and-neurodegenerative-disease_4207235.htmll 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://www.thegatewaypundit.com/2022/08/terminal-list-hollywood-hit-series-starring-chris-pratt-influenced-current-events-within-department-defense/; https://twitter.com/P_McCulloughMD/status/1545464447027888130; https://twitter.com/P_McCulloughMD/status/1561494836833820672?s=20&t=E1pu_m7HAyKwq2i07zQGlQ&utm_source=substack&utm_medium=email; https://twitter.com/JustTruthSleuth/status/1550466208255750145?s=20&t=E1pu_m7HAyKwq2i07zQGlQ&utm_source=substack&utm_medium=email.

[45] See https://www.ronjohnson.senate.gov/2022/7/sen-johnson-points-out-conflicting-cdc-statements-on-surveillance-of-covid-19-vaccine-adverse-events (last accessed August 23, 2022).

and whether to politically support vaccine mandates and passports—has an urgent need to understand how the CDC, 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 CDC has uncovered and how those signals have been investigated. The public has an urgent need to understand how the CDC continues to reach its conclusion that the COVID-19 vaccines are safe.

A lack of transparency about how CDC 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 for the requested records, expedited processing of this request is warranted, and CDC should produce the data and information necessary to address this critically important public issue by immediately producing the information requested in this FOIA request.

More specifically, a determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter as required under 5 U.S.C. § 552(a)(6)(A)(i). Failure to respond in a timely manner shall be viewed as a denial of this request and CHD may immediately file an administrative appeal or other legal action.

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).

VI. CONCLUSION

By working together at the outset, CHD and your agency 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. Children's Health Defense welcomes an opportunity to discuss this request with you before you undertake your search or incur search or duplication costs.

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. We share a common mission to promote public health and transparency in government. Children's Health Defense looks forward to working with your agency on this request. If you do not understand any part of this request, please

contact me at [redacted] during normal business hours.

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

Thank you for your time and attention to this matter.

Sincerely yours,

Risa Evans
Senior Legal Fellow, Children's Health Defense, on behalf of Children's Health Defense
852 Franklin Ave., Suite 511,
Franklin Lakes, New Jersey, 07417.
[redacted]

EXHIBIT 3

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

August 25, 2022

Risa Evans
Children's Health Defense
c/o Children's Health Defense
852 Franklin Ave., Suite 511
Franklin Lakes, New Jersey 07417
Via email: risa.evans@childrenshealthdefense.org

Dear Ms. Evans:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated August 23, 2022. Your request assigned number is 22-02105-FOIA, and it has been placed in our complex processing queue.

Extension of Time

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

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

x We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.
x We reasonably expect to receive and review voluminous records in response to your request.
xWe reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request LaShonda Schofield at 770-488-6241 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing

You requested that we expedite processing your request. Your request is granted and your FOIA request would be processed as quickly as possible.

Fee Category

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

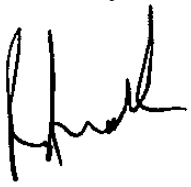
Cut-off-date

If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6241 or via email at hur7@cdc.gov.

We reasonably anticipate that you should receive documents by December 19, 2022. Please know that this date roughly estimates how long it will take the Agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



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

22-02105-FOIA

EXHIBIT 4

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

August 25, 2022

Risa Evans
Children's Health Defense
c/o Children's Health Defense
852 Franklin Ave., Suite 511
Franklin Lakes, New Jersey 07417
Via email: risa.evans@childrenshealthdefense.org

Dear Ms. Evans:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of August 23, 2022, assigned #22-02105-FOIA, regarding your attached request.

However, we are unable to process your request as it is currently stated. Even when we are able to determine precisely what records a requester seeks, we are not obliged to process it if doing so would be unduly burdensome or otherwise unreasonably strain limited agency resources due to the need to locate, review, redact and assemble a vast quantity of material. The courts have noted that the FOIA was not intended to reduce government agencies to full-time investigators on behalf of requesters.

Consequently, the scope of your request must be substantially narrowed if you wish for us to proceed with any search for responsive documents. Please clarify your request using the below:

- specify the corresponding CDC records custodians and/or organizations and provide names and email addresses (or domains)
- specify the type of communications (e.g. emails)

Please email your response to me at hur7@cdc.gov, no later than September 21, 2022. If you fail to submit a reasonable request by that date, we will consider your request withdrawn. Your request will be administratively closed, and no further action will be taken in regard to it.

Sincerely,

s/ LaShonda Schofield

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

22-02105-FOIA

EXHIBIT 5

Children's Health Defense

Risa Evans [redacted]

Your CDC FOIA Request #22-02105-FOIA

Risa Evans [redacted] Tue, Aug 30, 2022 at 1:59 PM
To: [redacted]

Dear Ms. Schofield--

I'm writing in response to your "Unduly Burdensome" letter of August 25, 2022. The letter requests that we:

- specify the corresponding CDC records custodians and/or organizations and provide names and email addresses (or domains)
- specify the type of communications (e.g. emails)

I previously reached out to you for clarification, but have not received a response and would like to keep things moving, so below are responses that I hope will sufficiently address your request for more information. Please let me know if you need further info, or if a conversation would be helpful. Thank you!
Risa

With respect to item 1 in CHD's FOIA request #22-02105 (PRR records), this item seeks PRR records generated pursuant to the VAERS SOP, and links to the VAERS SOP, which fully describes the CDC's PRR work. I believe the records would be located within the Division of Healthcare Quality Promotion, most likely within the Immunization Safety Office and the Surveillance Branch. If this information is insufficient to locate the records, please let me know.

With respect to item 2 in CHD's FOIA request #22-02105 (records of communications about PRR results and follow-up investigation), we are seeking email and text communications, and any other reports, papers, presentations, or data generated within or received by the CDC in connection with the PRR results. As indicated in the original FOIA request, the VAERS SOP fully describes the activities and communications for which the records are sought and the activities were additionally described in the CDC's spokeswoman's statements to the Epoch Times. I believe that the likely custodians are the same as those for Item 1: Division of Healthcare Quality Promotion, most likely within the Immunization Safety Office and the Surveillance Branch. If this information is insufficient to locate the records, please let me know.

With respect to item 3 in CHD's FOIA request #22-02105 (records of communications containing certain search terms listed in the FOIA request), we are seeking email and text communications and any other reports or data generated in connection with the listed search terms. As indicated in the original FOIA request, the VAERS SOP fully describes the activities and communications for which the records are sought, so there should be no ambiguity, but I am happy to provide more information if the request is unclera. I believe that the likely custodians are the same as those for the items above: Division of Healthcare Quality Promotion, most likely within the Immunization Safety Office and the Surveillance Branch. If this information is insufficient to locate the records, please let me know.

With respect to item 4 in CHD's FOIA request #22-02105 (copies of or links to data, etc. supporting CDC's statement comparing data mining techniques), the spokeswoman who referenced the records may be a custodian of those records; additionally, I would expect the Division of Healthcare Quality Promotion to be able to provide those records.

Thank you again, and please reach out if any more information or a conversation would be helpful.
[Quoted text hidden]

Children's Health Defense

Risa Evans [redacted]

Your CDC FOIA Request #22-02105-FOIA

Schofield, LaShonda (CDC/OCOO/OD) [redacted] Tue, Sep 6, 2022 at 8:38 AM
To: Risa Evans [redacted]

Good morning, Risa, Thank you for your response.

[Quoted text hidden]

EXHIBIT 6

September 7, 2022

FOIA OFFICE,
Centers for Disease Control & Prevention/
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

VIA CDC'S ONLINE FOIA PUBLIC ACCESS LINK

Re: Freedom of Information Act Request for Daily Priority Reports from CDC's VAERS contractor in connection with COVID-19 vaccine adverse events reported to VAERS

To Whom it May Concern:

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,[1] website,[2] newsletter, press briefings, media channel,[3] and social media platforms.[4]

The Centers for Disease Control and Prevention's (CDC) January 2021 "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)" (VAERS SOP) describes the CDC's plans to monitor VAERS for COVID-19 vaccine safety signals, and to follow up on any potential signals. The VAERS SOP promises that the CDC will—among other things— receive daily email alerts, called "Daily Priority Reports," from CDC's VAERS contractor, with a list of VAERS ID numbers for all reports of adverse events of special interest (AESIs) after COVID-19 vaccines.[5]

After CHD requested the Daily Priority Reports from the Food & Drug Administration (FDA) (FOIA #2022-5587), a member of the FDA's Center for Biologics Evaluation and

[1] *See* https://childrenshealthdefense.org/defender/
[2] *See* https://childrenshealthdefense.org/
[3] *See* CHD.TV https://live.childrenshealthdefense.org/
[4] *See* https://www.facebook.com/ChildrensHealthDefense, https://twitter.com/ChildrensHD, https://rumble.com/user/childrenshealthdefense.
[5] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 12.

Research FOIA staff indicated that the CDC is the custodian of these records and suggested we file this FOIA with the CDC.

Accordingly, pursuant to the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA") and the implementing regulations of your agency, 45 C.F.R Part 5, CHD requests the Daily Priority Reports described in the Centers for Disease Control and Prevention's (CDC) January 2021 "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021) (VAERS SOP), for the period of time from February 1, 2021, to the present.

The records are sought on an expedited basis.

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, CDC 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,[6] 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.

[6] 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.

- 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.

- 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.

Request for Fee Waiver

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 CDC —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 CDC 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.[7] 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, and other media. The organization makes materials it gathers available on its public website[8] and through its newsletter, and promotes the availability of these materials on social media platforms, such as Twitter.[9]

[7] *See* 5 U.S.C. § 552(a)(4)(A)(iii).
[8] *See* Children's Health Defense, https://childrenshealthdefense.org/.
[9] *See* https://twitter.com/ChildrensHD.

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, The Defender.[10]

Accordingly, CHD qualifies for a fee waiver.

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 CDC'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,[11] website,[12] newsletter, press briefings, media channel,[13] and social media platforms.[14]

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,[15] blogs,[16] articles,[17] essays,[18] podcasts[19] and videos.[20] 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

[10] *See* The Defender https://childrenshealthdefense.org/defender/.
[11] *See* https://childrenshealthdefense.org/defender/
[12] *See* https://childrenshealthdefense.org/
[13] *See* CHD.TV https://live.childrenshealthdefense.org/
[14] *See* https://www.facebook.com/ChildrensHealthDefense, https://twitter.com/ChildrensHD, https://rumble.com/user/childrenshealthdefense.
[15] *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).
[16] *See* https://childrenshealthdefense.org/defender/
[17] *See e.g.,* https://childrenshealthdefense.org/defender/ivermectin-beats-meds-treating-omicron/
[18] *See e.g.,* https://childrenshealthdefense.org/defender/cory-zue-coming-clean-stand-against-covid-vaccines/
[19] *See* The Defender Podcast, Robert F. Kennedy, Jr., https://podcasts.apple.com/us/podcast/rfk-jr-the-defender-podcast/id1552000243
[20] *See* https://live.childrenshealthdefense.org/

transparency with respect to the CDC'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 general public[21]; providing funding for broad-based vaccine distribution efforts throughout the United States;[22] imposing nationwide COVID-19 vaccine mandates;[23] paying billions of dollars to media sources to provide positive coverage of COVID-19 vaccines,[24] and working with social media companies to ensure positive coverage of COVID-19 vaccines and censor alternative viewpoints.[25]

The federal government's push towards universal COVID-19 vaccination has been aided through mandates imposed by businesses, schools, and state and local governments, on students, employees, and customers.[26] And now that the FDA has authorized booster shots for children and adults,[27] along with COVID-19 vaccines for

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[21] *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).

[22] *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 August 23, 2022).

[23] *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 August 23, 2022).

[24] *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 DHHS, "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 August 23, 2022).

[25] *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).

[26] *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; (last August 23, 2022).

[27] *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-

children as young as six months,[28] the push towards universal vaccination has only intensified.[29]

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.[30]

The CDC among other agencies, has assured the public that it is vigilantly monitoring the COVID-19 vaccine for safety.[31] For example, on a webpage entitled "Safety of COVID-19 Vaccines," the CDC proclaims:[32]

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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).

[28] *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).

[29] *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).

[30] 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.

[31] *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).

[32] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html?s_cid=10507:covid%20vaccine%20safety:sem.ga:p:RG:GM:gen:PTN:FY21 (last accessed August 17, 2022).

What You Need to Know

- COVID-19 vaccines are **safe and effective**.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in US history.
- CDC recommends COVID-19 vaccines for everyone 6 months and older and boosters for everyone 5 years and older, if eligible.

A crucial part of the CDC's COVID-19 vaccine safety monitoring is through the Vaccine Adverse Events Reporting System (VAERS). As described by the CDC, VAERS is the nation's "early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration."[33] The CDC's January 2021 "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)" (VAERS SOP) indicates that the CDC and FDA are to perform "routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines."[34] The VAERS SOP describes in detail the safety monitoring methods to be used, including the daily email reports sought in this FOIA request. As of September 7, 2022, the VAERS SOP is still posted on the CDC's website, in unmodified form.

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,[35] and there has been ongoing public weighing of the risks and benefits of the vaccines,[36] and ongoing public debate about

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[33] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html (last accessed August 17, 2022).

[34] *See* VAERS SOP at p. 3.

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

[36] 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*

public health policy, including the wisdom, legality, and morality of COVID-19 vaccine mandates and passports.[37]

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 CDC, a federal government agency, has followed through on its promise to vigilantly monitor the safety of COVID-19 vaccines. In particular, VAERS monitoring is currently a matter of tremendous public concern, as evidenced most recently by Sen. Ron Johnson's July 26 press release regarding the matter, coupled with his follow-up letter to CDC Director Rochelle Walensky.[38]

A lack of transparency about how CDC 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. Indeed, a lack of transparency in the U.S. public health agencies may explain why members of the public are turning in droves to online newsletters written by journalists, scientists, attorneys, and physicians who are working independently to investigate and analyze the safety of COVID-19 vaccines.[39]

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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;

[37] 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)

[38] See https://www.ronjohnson.senate.gov/2022/7/sen-johnson-points-out-conflicting-cdc-statements-on-surveillance-of-covid-19-vaccine-adverse-events (last accessed August 23, 2022).

[39] [39] For just a few examples of the independent pharmacovigilance work and reporting that has become essential reading for members of the public in the absence of federal transparency, *see, e.g.*, https://rwmalonemd.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Frobert%2520malone&utm_medium=reader2l; https://stevekirsch.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&ut

Because there is compelling need, expedited processing of this request is warranted, and CDC 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 CDC 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. Children's Health Defense looks forward to working with your agency on this request. If you do not understand any part of this request, please contact me at [redacted] during normal business hours.

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

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https://jessicar.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Fjessica%2520rose&utm_medium=reader2;
https://www.coffeeandcovid.com/?utm_source=%2Fsearch%2Fcoffee%2520and%2520covid&utm_medium=reader2&utm_campaign=reader2;
https://merylnass.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Fmeryl%2520nass&utm_medium=reader2;
https://roundingtheearth.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Frounding%2520the%2520earth&utm_medium=reader2;
https://naomiwolf.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Fnaomi%2520wolf&utm_medium=reader2;
https://tobyrogers.substack.com/?utm_source=substack&utm_medium=web&utm_campaign=reader2&utm_source=%2Fsearch%2Ftoby%2520rogers&utm_medium=reader2. *See also*, the heroic effort by public health and medical professionals to bring transparency to the discussion of vaccine safety, https://phmpt.org/.

Thank you for your time and attention to this matter.

Sincerely yours,

Risa Evans
Senior Legal Fellow, Children's Health Defense, on behalf of Children's Health Defense
852 Franklin Ave., Suite 511,
Franklin Lakes, New Jersey, 07417.
[redacted]

EXHIBIT 7

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

September 7, 2022

Risa Evans
Children's Health Defense
c/o Children's Health Defense
852 Franklin Ave., Suite 511
Franklin Lakes, New Jersey 07417
Via email: risa.evans@childrenshealthdefense.org

Dear Ms. Evans:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated September 7, 2022. Your request assigned number is 22-02151-FOIA, and it has been placed in our complex processing queue.

Extension of Time

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

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

x We reasonably expect to receive and review voluminous records in response to your request.
x We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request LaShonda Schofield at 770-488-6241 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Expedited Processing

You requested that we expedite processing your request. Your request is granted and your FOIA request would be processed as quickly as possible.

Fee Category

Because you are considered a “News Media requester,” you will not be charged fees unless you choose to receive responsive records in hard copy. (10 cents/page)

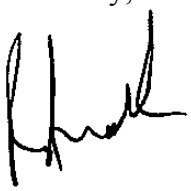
Cut-off-date

If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6241 or via email at hur7@cdc.gov.

We reasonably anticipate that you should receive documents by December 30, 2022. Please know that this date roughly estimates how long it will take the Agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



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

22-02151-FOIA