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._____**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

This Complaint concerns two Freedom of Information Act (FOIA) requests that Children's Health Defense (CHD) submitted to the Centers for Disease Control and Prevention (CDC) in the summer of 2022, seeking records in connection with the CDC's safety-monitoring of COVID-19 injections through the Vaccine Adverse Events Reporting System (VAERS). To date, CDC has not provided a determination on, or records responsive to, either request. CHD now brings this action to compel compliance with the FOIA, 5 U.S.C. § 552 ("FOIA").

PARTIES

1. Plaintiff Children's Health Defense (CHD) is a not-for-profit organization incorporated under the laws of California and has a mailing address of 852 Franklin Ave., Suite 511, Franklin Lakes, New Jersey, 07417.

2. CHD works to end disease epidemics by exposing causes, eliminating harmful exposures, holding those responsible accountable, seeking justice for those injured, and establishing safeguards to prevent future harm. CHD is committed to educating the general public in connection with these efforts.[1] As part of its mission, CHD regularly requests records from federal agencies pursuant to FOIA.

3. Defendant Centers for Disease Control and Prevention (CDC), an agency within the executive branch of the U.S. Government, is headquartered at 1600 Clifton Road, N.E., Atlanta, GA 30329. CDC is a federal agency within the meaning of 5 U.S.C. § 552(f), and has possession, custody, and control of records to which Plaintiff seeks access.

JURISDICTION AND VENUE

4. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

FACTS

A. Background for CHD's FOIA Requests

1. The Federal Government's Promotion of COVID-19 Injections

5. For more than two years, the U.S. government has engaged in ongoing, relentless efforts to promote COVID-19 injections. These efforts include spending billions of dollars on

[1] *See* Children's Health Defense Website at https://childrenshealthdefense.org/; *The Defender*, Children's Health Defense News & Views, at https://childrenshealthdefense.org/defender/.

injections;[2] funding broad-based distribution efforts throughout the United States;[3] imposing nationwide vaccine mandates;[4] paying billions of dollars to media sources to promote the injections;[5] and working with social media companies to ensure positive coverage of the injections and to censor other viewpoints.[6]

6. Numerous scientists, physicians, public health experts, and other concerned

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[2] *See, e.g., Biden-Harris Administration secures 105 million doses of Pfizer's latest COVID-19 vaccine for fall vaccination campaign*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (Jun. 29, 2022), 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 January 12, 2023).

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

[4] *See, e.g., Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees*, THE WHITE HOUSE (Sept. 09, 2021), Executive Order on Covid Safety Protocols for Federal Contractors; Details on OSHA and CMS Vaccination Requirements.

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

[6] *See, e.g.*, Aaron Kheriaty, MD, *Our Lawsuit Uncovers Army of Federal Bureaucrats Coercing Social-Media Companies to Censor Speech*, HUMAN FLOURISHING (Sept. 1, 2022), https://aaronkheriaty.substack.com/p/our-lawsuit-uncovers-army-of-federal?utm_source=brownstone&utm_medium=web; *AFL Lawsuit Reveals Damning CDC Documents Proving Government Collusion With Big Tech to Censor Free Speech and Promote Biden Administration Propaganda*, AMERICA FIRST LEGAL (Jul. 27, 2022), https://aflegal.org/afl-lawsuit-reveals-damning-cdc-documents-proving-government-collusion-with-big-tech-to-censor-free-speech-and-promote-biden-administration-propaganda/; Ryan Mills, *Twitter Files: Platform Suppressed Valid Information from Medical Experts about Covid-19*, NATIONAL REVIEW (Dec. 26, 2022), https://www.nationalreview.com/news/twitter-files-platform-suppressed-valid-information-from-medical-experts-about-covid-19/; AG Bailey, *Missouri Attorney General Releases More Documents Exposing White House's Social Media Censorship Scheme*, News, Andrew Bailey, Missouri Attorney General (Jan.9, 2023), https://ago.mo.gov/home/news/2023/01/09/missouri-attorney-general-releases-more-documents-exposing-white-house's-social-media-censorship-scheme.

individuals have questioned the safety of COVID-19 injections,[7] and many thousands of post-injection adverse events have been reported to the federal government.[8]

7. However, throughout the COVID-19 pandemic, the federal government has continued to tout COVID-19 injections as "safe and effective," and to assure the public that federal agencies are vigilantly monitoring their safety.[9] For example, a CDC webpage titled "Safety of COVID-19 Vaccines," proclaims as follows:[10]

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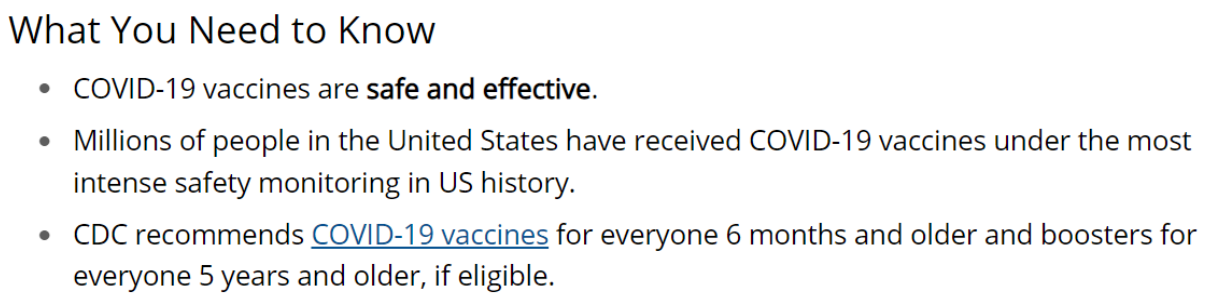
[7] *See, e.g.*, Kyle A. Beattie, *750+ Studies About the Dangers of the COVID-19 Injections* (Mar. 31, 2022), https://img1.wsimg.com/blobby/go/058ad340-73c5-4f3d-af4f-8df4795d5196/750-Studies-About-the-Dangers-of-the-COVID-19-.pdf; *The Pfizer Inoculations for Covid-19: More Harm Than Good*, CANADIAN COVID CARE ALLIANCE, https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf; Video: *Live in D.C.: Expert Panel on Medical Mandates & Vaccine Injuries*, THE HIGHWIRE, https://thehighwire.com/videos/live-in-d-c-expert-panel-on-medical-mandates-vaccine-injuries/.

[8] For example, as of January 6, 2023, VAERS (which is just one of government's data bases of vaccine injuries) showed 33,591 reports of deaths, 188,857 reports of hospitalization, 26,166 reports of myo- and pericarditis, and 62,019 reports of permanent disability following COVID-19 vaccination. *VAERS COVID Vaccine Adverse Event Reports*, Covid Vaccine Data, OPENVAERS (through Jan. 13, 2023), https://www.openvaers.com/covid-data. Notably, the VAERS underreporting factor appears to be significant. *See* Steve Kirsch, *Why won't the CDC or FDA reveal the VAERS URF?*, TS NEWS (Oct. 25, 2021), https://www.trialsitenews.com/a/why-wont-the-cdc-or-fda-reveal-the-vaers-urf; Steve Kirsch, *Latest VAERS estimate: 388,000 Americans killed by the COVID vaccines*, STEVE KIRSCH'S NEWSLETTER (Dec. 14, 2021), https://stevekirsch.substack.com/p/latest-vaers-estimate-388000-americans?utm_source=%2Fsearch%2Furf&utm_medium=reader2 and report linked thereto by Steve Kirsch, Jessica Rose, Mathew Crawford, *Estimating the number of COVID vaccine deaths in America* (last updated Dec. 24, 2021), https://www.skirsch.com/covid/Deaths.pdf; Jessica Rose, *A question and answer document on the subject of VAERS as a pharmacovigilance tool*, UNACCEPTABLE JESSICA (Aug. 9, 2022), https://jessicar.substack.com/p/a-question-and-answer-document-on#footnote-1.

[9] *See, e.g.*, *Safety of COVID-19 Vaccines*, CENTERS FOR DISEASE CONTROL AND PREVENTION (updated Jan. 23, 2023), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html; *COVID-19 Vaccine Safety Surveillance*, Summaries of Monitoring Efforts, U.S. FOOD & DRUG ADMINISTRATION (Dec. 7, 2021), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts.

[10] *See Safety of COVID-19 Vaccines*, *supra*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.



2. The CDC's Duty to Detect Safety Signals through VAERS

8. A crucial part of the federal government'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."[11]

9. 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."[12]

10. The CDC's January 2021 *Vaccine Adverse Event Reporting System* (*VAERS*) *Standard Operating Procedures for COVID-19* (*as of 29 January 2021*) indicates that the CDC and FDA are to perform "routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines."[13]

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

[12] *Id.*

[13] *See* VAERS Team, *Vaccine Adverse Event Reporting System* (*VAERS*) *Standard Operating Procedures for COVID-19* (*as of 29 January 2021*), CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf (hereinafter "VAERS SOP"), at 3.

11. The VAERS Standard Operating Procedure (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."[14]

12. The VAERS SOP details the CDC's specific safety-monitoring obligations and promises that—among other things—the CDC will do the following:

- Receive daily email alerts ("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;[15]
- 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;[16]
- Monitor the trend of PRR and data mining results to help determine when to initiate a clinical review of Adverse Events of Special Interest, such review to include review of medical records, time from vaccination to symptom onset, patient history and course of illness, and more;[17]

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

[15] *See* VAERS SOP, *supra*, at 12.

[16] *Id.* at 11, 14, 16.

[17] *Id*. at 11, 18.

- Hold weekly VAERS Team COVID-19 meetings to analyze and interpret VAERS data and discuss signals or potential events of concern;[18]
- Provide monthly summary of this data review to pertinent stakeholders, such as Immunization Safety Office (ISO) leadership and FDA partners;[19]
- Share and discuss the results of data mining analyses and signals with the FDA through weekly vaccine safety coordination meetings among ISO team members and FDA.[20]

3. The CDC's Conflicting Statements About its Own VAERS-Monitoring Efforts

13. In June 2022, in response to a FOIA request in which CHD sought PRR and other safety-monitoring records from February 2021 through September 2021, the CDC told CHD that "no PRRs were conducted by CDC" and data mining is outside of the agency's purview. *See* Exhibit 1, Final Response to FOIA 22-01479.[21]

14. However, in July 2021, CDC told the *Epoch Times* that it "has been performing PRRs since February 2021 and continues to do so to date."[22]

15. In August 2021, the CDC again revised the description of its VAERS-monitoring activity, telling the *Epoch Times* that it performed PRRs for a four-month period, from March 25,

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[18] *Id*. at 19.

[19] *Id*. at 18.

[20] *Id*. at 11, 19.

[21] *See CDC Admits It Never Monitored VAERS for COVID Vaccine Safety Signals*, the Defender, CHILDREN'S HEALTH DEFENSE (Jun. 21, 2022), https://childrenshealthdefense.org/defender/cdc-vaers-covid-vaccine-safety/.

[22] *See* Zachary Stieber, *EXCLUSIVE: CDC Says It Performed Vaccine Safety Data Mining After Saying It Didn't*, THE EPOCH TIMES (Jul. 23, 2022) https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html.

2022 to July 31, 2022.[23] CDC indicated "PRR results were generally consistent with EB [Empirical Bayesian] data mining, revealing 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."[24]

16. In January 2023, the *Epoch Times* reported that the CDC disclosed PRR analysis conducted in July 2022, which revealed hundreds of safety signal for COVID-19 vaccines.[25]

B. CHD's FOIA Requests

1. First Request (#22-02105)

17. On August 23, 2022, CHD submitted a FOIA request to CDC seeking records of safety monitoring conducted by the CDC pursuant to the VAERS SOP, as follows:

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

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[23] *See* The Epoch Times (), https://www.theepochtimes.com/exclusive-cdc-admits-it-gave-false-information-about-covid-19-vaccine-surveillance_4657836.html.

[24] *Id*.

[25] *See* Zachary Stieber, *EXCLUSIVE: CDC Finds Hundreds of Safety Signals for Pfizer and Moderna COVID-19 Vaccines*, THE EPOCH TIMES (Jan. 3, 2023), https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines_4956733.html; Josh Guetzkow, *CDC Finally Released Its VAERS Safety Monitoring Analyses for COVID Vaccines via FOIA*, JACKANAPES JUNCTION (Jan. 4, 2023), https://jackanapes.substack.com/p/cdc-finally-released-its-vaers-safety?utm_source=post-email-title&publication_id=747747&post_id=91051374&isFreemail=true&utm_medium=email,

CDC and between CDC and FDA, to the extent not already provided in response to numbers 1 and 2 above;

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.

See Exhibit 2, First Request.

18. CHD requested expedited processing, noting that it will widely publicize the records through its newsletter and online streaming platform, and there is an urgent need for the information, both to help the public make fully informed medical and political decisions and to maintain trust in federal public health agencies. *See id*.

19. On August 25, 2022, CDC acknowledged receipt of the First Request and assigned it FOIA #2022-02105. *See* Exhibit 3, Acknowledgment of First Request. The letter granted expedited processing, also indicating that the request was complex, and that CHD should receive documents by December 19, 2022. *See id*.

20. On August 25, CDC in a separate letter indicated that the request was unduly burdensome, and that without clarifications of the records custodians and types of communications sought, the request would be administratively closed. *See* Exhibit 4, Unduly Burdensome Letter.

21. On August 30, 2022, by email, CHD clarified the request, identifying what it believed to be the custodians of the various records sought, and indicating the types of communications sought. *See* Exhibit 5, Clarification Email and Response. On September 6, 2022, CDC thanked CHD for the clarification. *See id*. As of the filing of this complaint, CDC has not sought further clarification.

22. On October 12 and November 11, 2022, CHD emailed CDC about the status of the First Request. CDC responded to the November 11 email by letter, estimating that the

records could be expected by the date provided in the Acknowledgment Letter, December 19, 2022. On January 12, 2023, CHD inquired about the status of the First Request, and requested the records. As of the filing of this complaint, CDC has not responded to the January 12 inquiry, and has not provided any records or a determination on the request.

2. Second Request (#22-02151)

23. On September 7, 2022, CHD submitted the Second Request to CDC, seeking the daily email alerts ("Daily Priority Reports") from the CDC's VAERS contractor, listing VAERS ID numbers for all AESI's, as described in the VAERS SOP. CHD sought these daily reports for the period of time from February 1, 2021, to the filing of the request. *See* Exhibit 6, Second Request.

24. CHD sought expedited processing, for the reasons noted in the First Request. *See id*.

25. On September 7, 2022, CDC acknowledged receipt of the Second Request, and granted expedited processing. The Acknowledgment Letter anticipated the records would be provided to CHD by December 30, 2022. *See* Exhibit 7, Acknowledgment of Second Request.

26. On October 12 and November 11, 2022, CHD emailed CDC about the status of the Second Request. CDC responded to the November 11 email by letter, estimating that the records could be expected by the date provided in the Acknowledgment Letter, December 30, 2022. On January 12, 2023, CHD inquired about the status of the Second Request, and requested the records. As of the filing of this complaint, CDC has not responded to the January 12 inquiry, and has not provided any records or a determination on the request.

COUNT I (First Request #2022-02105)

27. The previous allegations are incorporated herein by reference.

28. The FOIA authorizes this Court to provide relief when an agency has improperly withheld agency records. *See Kissinger v. Reporters Committee for Freedom of the Press*, 445 U.S. 136, 150 (1980).

29. Applicable time limits have long since passed. *See* 5 U.S.C. § 552(a)(3)(A) (requiring that an agency "promptly" make public records available to anyone who submits properly formulated FOIA request); 5 U.S.C. § 552(a)(6)(A)(i) (setting forth time-limits for final determination); 5 U.S.C. § 552(a)(6)(B)(i)-(iii) (setting forth limited circumstances for ten-day extension); 5 U.S.C. § 552(a)(6)(C) (deeming administrative remedies exhausted upon agency's failure to comply with applicable time limits).

30. CDC has violated the FOIA through its failure to provide a final determination and its failure to provide the records to which CHD is entitled.

COUNT II (Second Request, #2022-02151)

31. The previous allegations are incorporated herein by reference.

32. The FOIA authorizes this Court to provide relief when an agency has improperly withheld agency records. *See Kissinger v. Reporters Committee for Freedom of the Press*, 445 U.S. 136, 150 (1980).

33. Applicable time limits have long since passed. *See* 5 U.S.C. § 552(a)(3)(A) (requiring that an agency "promptly" make public records available to anyone who submits properly formulated FOIA request); 5 U.S.C. § 552(a)(6)(A)(i) (setting forth time-limits for final determination); 5 U.S.C. § 552(a)(6)(B)(i)-(iii) (setting forth limited circumstances for ten-day extension); 5 U.S.C. § 552(a)(6)(C) (deeming administrative remedies exhausted upon agency's failure to comply with applicable time limits).

34. CDC has violated the FOIA through its failure to provide a final determination and its failure to provide the records to which CHD is entitled.

REQUESTED RELIEF

Pursuant to 5 U.S.C. § 552(a)(4)(B) and 5 U.S.C. § 552(a)(4)(E)(i), CHD respectfully requests that the Court provide the following relief:

(A) Provide for expeditious proceedings in this action;

(B) Declare CDC's failures to timely comply with the FOIA unlawful;

(C) Order CDC to conduct a search for any and all records responsive to each request and to demonstrate that it employed search methods reasonably likely to lead to the discovery of responsive records;

(D) Order FDA to produce all non-exempt records responsive to each request no later than 20 days from the date of the court's ruling, along with a *Vaughn* index of any responsive records withheld under a claim of exemption;

(E) Enjoin CDC from continuing to withhold non-exempt records responsive to CHD's FOIA requests;

(F) Grant CHD an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

(G) Grant such other and further relief as the Court deems just and proper.

Dated: February 16, 2023

Respectfully submitted,

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