UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

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

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

This Complaint concerns two Freedom of Information Act (FOIA) requests Children's Health Defense (CHD) submitted to the U.S. Food and Drug Administration (FDA) in the summer and early fall of 2022, seeking records in connection with the FDA's safety-monitoring of COVID-19 injections through the Vaccine Adverse Events Reporting System (VAERS). The FDA denied the First Request *in toto*. The FDA claimed a blanket exemption, arguing that under 5 U.S.C. §552(b)(5), the records are protected as intra-agency memoranda within the deliberative process of FDA, as attorney work product, and as attorney-client communications. The FDA has not provided any determination on or records responsive to the Second Request. CHD now brings this action to compel compliance with 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 health 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 Food and Drug Administration (FDA) is an agency within the executive branch of the U.S. Government, headquartered at 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993. FDA 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

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

efforts to promote COVID-19 injections. These efforts include spending billions of dollars on 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]

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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.

6. Numerous scientists, physicians, public health experts, and other concerned 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, on a web page entitled *COVID-19 Vaccine Safety Surveillance* (U.S. FOOD & DRUG ADMINISTRATION (Dec. 7, 2021),

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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.

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance), the FDA states it is "conducting intensive monitoring of COVID-19 vaccine safety in the U.S. using a variety of approaches. Based on available information, FDA strongly believes that the known and potential benefits of COVID-19 vaccination greatly outweigh their known and potential risks."[10]

2. Federal Public Health Agencies' Detection of 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 Centers for Disease Control and Prevention (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]

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[10] *See COVID-19 Vaccine Safety Surveillance*, Summaries of Monitoring Efforts, *supra*, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts. On the surveillance webpage, the FDA summarizes the safety monitoring efforts being undertaken through the Center for Biologics Evaluation and Research (CBER), including surveillance of the Vaccine Adverse Events Reporting System (VAERS). *See id.*

[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.*

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]

11. 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."[14]

12. The VAERS SOP promises that the FDA will, among other things:

- Routinely conduct manual review of reports of serious Adverse Events of Special Interest ("AESIs");[15]
- Conduct Empirical Bayesian (EB) data mining to identify adverse events reported more frequently than expected, and share and discuss results and signals with the CDC;[16]
- Receive and discuss the results of the CDC's own PRR data mining, including the results and signals;[17]
- Consult with VAERS staff of the CDC's Immunization Safety Office to coordinate further investigation if a signal is detected.[18]

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[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.

[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] VAERS SOP, *supra*, at 11, 12, 20.

[16] VAERS SOP, *supra*, at 16-17.

[17] VAERS SOP, *supra*, at 17.

[18] VAERS SOP, *supra*, at 16-17, 19.

13. Pursuant to a FOIA request by *The Epoch Times*, the CDC recently released PRR analysis it conducted pursuant to the VAERS SOP from December 14, 2020 to July 29, 2022, which revealed hundreds of safety signal for COVID-19 vaccines.[19] According to *The Epoch Times*, CDC indicated that the PRR results "were generally consistent with EB data mining" and that they "generally corroborated findings from Empirical Bayesian (EB) data mining."[20]

14. Although the FDA has not publicly released its EB data, members of the FDA's Center for Biologics Evaluation and Research (CBER) relied on some of this data in a published article, entitled ***Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021*** (B. Day et al., MEDRXIV 2022.05.05.22274695, https://doi.org/10.1101/2022.05.05.22274695, https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.full), which concludes that reporting rates for death following COVID-19 vaccines were lower than expected all-cause death rates.[21]

15. Additionally, in a recent announcement about ischemic stroke safety signals, the FDA stated, "[t] he Vaccine Adverse Event Reporting System (VAERS) managed by CDC and FDA has not seen an increase in reporting of ischemic strokes following the updated (bivalent) vaccine." [22]

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[19] *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.

[20] *See* Zachary Stieber, *CDC Finds Hundreds of Safety Signals for Pfizer and Moderna COVID-19 Vaccines*, *supra*.

[21] B. Day et al., *VAERS Death Reports Following COVID-19 Vaccination*, *supra*, at 1, 9-10, 12.

[22] See *CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older*, U.S. FOOD & DRUG ADMINISTRATION (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older?utm_source=substack&utm_medium=email.

B. CHD's First FOIA Request (#2022-5587/Appeal #22-000123AA)

16. On July 27, 2022, CHD submitted a FOIA request seeking, on a fee-waived basis, records of safety monitoring conducted by the FDA pursuant to the VAERS SOP, as follows:

1. Records of daily email alerts/Daily Priority Reports received by FDA and/or CBER from CDC's VAERS contractor, including but not limited to any lists of VAERS ID numbers for reports of adverse events of special interest (AESIs) after COVID-19 vaccines;[23]
2. Records of any manual review of serious AESI reports conducted by FDA and/or CBER;[24]
3. Records of any Empirical Bayesian data mining conducted by FDA and/or CBER, and records of any sharing or discussion of results and signals with the CDC;[25]
4. Records of any results and signals received by FDA and/or CBER from the CDC's own PRR data mining, and any discussion of those results;[26]
5. Records of any consultations by FDA and/or CBER with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected.[27]
6. Records of the Empirical Bayesian data mining conducted on or about November 17, 2021, as described in *VAERS Death Reports Following COVID-19 Vaccination*, *supra*.

See Exhibit 1, First Request.

17. 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.*

18. On August 2, 2022, FDA acknowledged receipt of the request and assigned it FOIA #2022-5587.

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

[24] *Id.*

[25] VAERS SOP, *supra*, at 16-17.

[26] VAERS SOP, *supra*, at 17.

[27] VAERS SOP, *supra*, at 16-17, 19.

19. The Acknowledgment Letter stated that FDA might be unable to comply with the twenty-working-day time limit, as well as the additional ten days provided by the FOIA. *See* Exhibit 2, Acknowledgment of First Request. The Acknowledgment Letter did not indicate that the FOIA request was unclear, overbroad, or otherwise improperly formulated. *See id.*

20. On August 8, 2022, FDA denied CHD's request for expedited processing. *See* Exhibit 3, Denial of Expedited Processing for First Request.

21. On September 7, 2022, after telephone communications with the FOIA office at CBER, CHD narrowed the scope of its request by withdrawing items (1) and (6). *See* Exhibit 4, Correspondence. As discussed below, CHD subsequently filed a new request for the records sought in item (6), i.e. records of the data mining underlying the Death Reporting Rates Article.

22. On October 4, 2022, the FDA provided a final response to the First Request, denying it *in toto*. *See* Exhibit 4, Correspondence.

23. The FDA's response claims a blanket exemption under 5 U.S.C. § 552(b)(5) and associated Department of Health and Human Services regulations, arguing the denial is authorized for two reasons: (1) because the requested records are "[i]ntra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable," and (2) because "the information also contains a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges as enunciated by the Supreme Court…" *See id*.

24. The response does not indicate that FDA has searched for any of the requested records. Indeed, the response does not even indicate whether the requested records exist.

25. To the extent the records do exist, the response does not provide any information about the number, type, or authors of the records.

26. To the extent the records do exist, the response does not provide any information about the context of the records, the nature of the deliberative process underlying the claimed exemption, or the role the records played in that process.

27. To the extent the records do exist, the response does not provide any information to support a claim of attorney-client or work-product privilege.

28. To the extent the records exist and contain some information that is exempt from disclosure, the response does not indicate why it is not possible to segregate and disclose the non-exempt information.

29. On October 11, 2022, CHD filed an administrative appeal. *See* Exhibit 5, Administrative Appeal of First Request. In the appeal, CHD requested that FDA:

1. immediately search for responsive records;
2. promptly provide all non-exempt records to CHD;
3. for any material alleged to be exempt, describe the withheld or redacted material, the context for the material, and the claimed exemption in sufficient detail to demonstrate how and why the exemption applies; and
4. for any non-exempt material that is not disclosed, explain why it is not reasonably segregable from exempt material.

See id.

30. On October 12, 2022, FDA acknowledged the Appeal and assigned it #22-000123AA. *See* Exhibit 4, Correspondence.

31. On November 12, 2022, after CHD inquired about a timeframe for the appeal, FDA indicated that the appeals process will take 9-12 months, with a final response "around" the summer of 2023. *See id*.

C. CHD's Second FOIA Request (#2022-6498)

32. On September 8, 2022, CHD submitted a FOIA request seeking on a fee-waived basis records of the Empirical Bayesian data mining underlying the analysis in B. Day et al.,

VAERS Death Reports Following COVID-19 Vaccination, *supra*. *See* Exhibit 6, Second Request.

33. On September 9, 2022, FDA acknowledged receipt of the request and assigned it FOIA #2022-6498. *See* Exhibit 7, Acknowledgment of Second Request.

34. The Acknowledgment Letter stated that FDA might be unable to comply with the twenty-working-day time limit, as well as the additional ten days provided by the FOIA. *See Id.* The Acknowledgment Letter did not indicate that the FOIA request was unclear, overbroad or otherwise improperly formulated. *See id.*

35. On October 12, 2022, CHD wrote to FDA requesting a final determination, or a date certain by which such determination could be expected. *See* Exhibit 4, Correspondence.

36. After receiving no response from FDA, on November 21, 2022, CHD wrote to FDA seeking a final determination. *See id.*

37. To date, FDA has not responded to CHD's emails, and has not provided records, a final determination, or a date by which either might be expected.

COUNT I (First Request #2022-5587/Appeal #22-000123AA)

38. The previous allegations are incorporated herein by reference.

39. 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).

40. Applicable FOIA 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).

41. FDA has violated the FOIA through its failure to search for or provide any of the records to which CHD is entitled, through its improper use of the "intra-agency memo exemption," 5 U.S.C. § 552(b)(5), and through its failure to rule on CHD's administrative appeal.

COUNT II (Second Request, #2022-6498)

42. The previous allegations are incorporated herein by reference.

43. 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).

44. 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).

45. FDA has violated the FOIA through its failure to provide a final determination and its failure to provide any of 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 FDA's failures to timely comply with the FOIA unlawful;

(C) Order FDA 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;

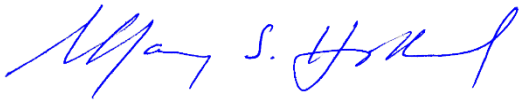
(E) Enjoin FDA from continuing to withhold non-exempt records responsive to CHD's FOIA requests;

(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: January 26, 2023

Respectfully submitted,



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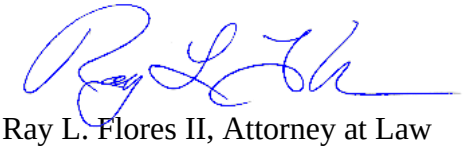

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UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

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

EXHIBITS TO COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

EXHIBIT 1

Children's Health Defense

July 27, 2022

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

Contact: Beth Brockner-Ryan

Main Line 240-402-7800
FOI Line 240-402-8008

Submitted via FDA's ONLINE FOIA PORTAL

Re: Freedom of Information Act Request for records of FDA and CBER's safety monitoring of VAERS in connection with COVID-19 vaccines

Dear Sir or Madam:

Children's Health Defense (CHD) respectfully requests that you provide the records described below.

Background

This FOIA request seeks records connected with safety monitoring of COVID-19 vaccines through the VAERS database.

On a web page entitled "COVID-19 Vaccine Safety Surveillance," the FDA states, "FDA is conducting intensive monitoring of COVID-19 vaccine safety in the U.S. using a variety of approaches. Based on available information, FDA strongly believes that the known and potential benefits of COVID-19 vaccination greatly outweigh their known and potential risks."[1]

[1] *See* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (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).

The webpage summarizes the COVID-19 vaccine safety monitoring efforts the FDA is undertaking through the Center for Biologics Evaluation and Research (CBER),[2] including surveillance through the Vaccine Adverse Events Reporting System (VAERS).

Although the COVID-19 Vaccine Safety Surveillance webpage does not describe how VAERS is surveilled by the FDA or CBER, the Centers for Disease Control's February 2021 "VAERS Monitoring Standard Operating Procedure" (VAERS SOP) describes VAERS monitoring methods to be used by the FDA, indicating that the FDA's will surveil VAERS by routinely reviewing all serious and other medically important condition (OMIC) reports daily, and by conducting data mining.[3] More specifically, the VAERS SOP promises the FDA 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;[4]
- Routinely conduct manual review of serious ASEI reports;[5]
- Conduct Empirical Bayesian data mining to identify adverse events reported more frequently than expected, and share and discuss results and signals with the CDC;[6]
- Receive and discuss the results of the CDC's own PRR data mining, including the results and signals;[7]
- Consult with VAERS staff of the CDC's Immunization Safety Office to coordinate further investigation if a signal is detected.[8]

In an article entitled "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021," ("Death Reporting Rates Article"), members of the FDA's Center for Biologics Evaluation and Research, along with others, concluded that reporting rates for death following COVID-19 vaccines were lower than expected all-cause death rates using various techniques, including Empirical Bayesian data mining (EB) conducted on November 17, 2021.[9]

Requested Records

This FOIA request follows up on the FDA's assurances of safety monitoring of VAERS by requesting information about the specific monitoring the FDA has done to

[2] *See* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance#Summaries%20of%20Monitoring%20Efforts (last accessed July 12, 2022).
[3] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 11, 20.
[4] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 12.
[5] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 12.
[6] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17.
[7] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 17.
[8] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17, 19.
[9] https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.full.pdf , at pp. 1, 9-10, 12.

date, and what this monitoring has revealed in terms of any connections or lack thereof between COVID-19 vaccination and adverse events.

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R Part 5, Children's Health Defense (CHD), a non-governmental organization, makes the following request for records in connection with the FDA's COVID-19 vaccine VAERS safety monitoring efforts.

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

As used in this request, "FDA," "CBER," and "CDC" mean each entity as a whole, as well as any officer, official, employee, or agent of the entity, and any subordinate division or entity.

For the period from February 1, 2021 through the present, please provide the following items. Items 1 through 5 are in reference to the VAERS SOP described above. Item 6 is in reference to the Death Reporting Rates Article.

1) Records of the daily email alerts/Daily Priority Reports received by FDA and/or CBER from CDC's VAERS contractor, including but not limited to any lists of VAERS ID numbers for reports of adverse events of special interest (AESIs) after COVID-19 vaccines;[10]
2) Records of any manual review of serious ASEI reports conducted by FDA and/or CBER;[11]
3) Records of any Empirical Bayesian data mining conducted by FDA and/or CBER, and records of any sharing or discussion of results and signals with the CDC;[12]
4) Records of any results and signals received by FDA and/or CBER from the CDC's own PRR data mining, and any discussion of those results;[13]
5) Records of any consultations by FDA and/or CBER with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected detected.[14]
6) Records of the Empirical Bayesian data mining conducted on or about November 17, 2021, as described in "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021."

[10] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf. at p. 12.
[11] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 12.
[12] /https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17.
[13] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 17.
[14] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17, 19.

Guidance Regarding the Search and Processing of Requested Records

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

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

- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,[15] 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. 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.

Fee Waiver Request

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

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[15] Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-pressoffice/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.

The American public has a significant interest in having a full understanding of how the FDA and its agents are monitoring the safety of COVID-19 vaccines. 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.[16] 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.

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.

CHD uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. The organization also makes materials it gathers available on its public website[17] and newsletter and promotes their availability on social media platforms, such as Facebook[18] and Twitter.[19]

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

Accordingly, CHD qualifies for a fee waiver.

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

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

health information and data and does so through its publication,[21] website,[22] newsletter, press briefings, media channel,[23] and social media platforms.[24]

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

There is a clear urgency and compelling need to inform the public concerning the FDA'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[31]; providing funding for broad-based vaccine distribution efforts throughout the United States;[32] imposing nationwide COVID-19 vaccine mandates;[33]

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[21] *See* https://childrenshealthdefense.org/defender/
[22] *See* https://childrenshealthdefense.org/
[23] *See* CHD.TV https://live.childrenshealthdefense.org/
[24] *See* https://www.facebook.com/ChildrensHealthDefense, https://twitter.com/ChildrensHD, https://rumble.com/user/childrenshealthdefense.
[25] *See e.g.,* https://childrenshealthdefense.org/defender/chd-tv-rfk-jr-defender-vanden-bossche-vaccinating-omicron-pandemic/, https://childrenshealthdefense.org/defender/meryl-nass-tessa-lena-under-attack/, (last accessed March 7, 2022).
[26] *See* https://childrenshealthdefense.org/defender/
[27] *See e.g.,* https://childrenshealthdefense.org/defender/ivermectin-beats-meds-treating-omicron/
[28] *See e.g.,* https://childrenshealthdefense.org/defender/cory-zue-coming-clean-stand-against-covid-vaccines/
[29] *See* The Defender Podcast, Robert F. Kennedy, Jr., https://podcasts.apple.com/us/podcast/rfk-jr-the-defender-podcast/id1552000243
[30] *See* https://live.childrenshealthdefense.org/
[31] *See, e.g.*, https://www.hhs.gov/about/news/2022/06/29/biden-harris-administration-secures-105-million-doses-of-pfizers-latest-covid-19-vaccine-for-fall-vaccination-campaign.html (last accessed July 14, 2022).
[32] *See* https://www.cdc.gov/media/releases/2021/p0407-covid-19-vaccine-programs.html#:~:text=The%20Centers%20for%20Disease%20Control,virus%20that%20causes%20COVID%2D19 (last accessed July 11, 2022).
[33] *See* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/, https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/ (last accessed July 11, 2022).

and paying billions of dollars to media sources to provide positive coverage of COVID-19 vaccines.[34]

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.[35] And now that the FDA has authorized booster shots for children and adults,[36] along with COVID-19 vaccines for children as young as six months,[37] the push towards universal vaccination has only intensified.[38]

During this push, numerous scientists, physicians, public health experts, and vaccine-injured individuals have questioned the safety of COVID vaccines.[39] Moreover, the

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[34] *See* https://www.congress.gov/bill/117th-congress/house-bill/1319/text; *see also*, https://www.hhs.gov/about/news/2021/04/01/hhs-launches-nationwide-network-trusted-voices-encourage-vaccination-next-phase-covid-19-public-education-campaign.html. According to the Department of Health and Human Services, "The [media campaign's] influencer strategy is to cultivate and collaborate with a range of influencers, including community leaders, celebrities, musicians, artists, entertainers, medical experts, and digital creators, to amplify Campaign messaging to target audiences. Our goal is to increase trust and confidence in the COVID vaccines with our key audiences by strategically leveraging an individual's influence with their followers." *See* https://wecandothis.hhs.gov/resource/campaign-approach-to-reaching-general-audiences#paid-media (last accessed July 11, 2022).

[35] *See, e.g.,* https://www.kff.org/report-section/state-covid-19-data-and-policy-actions-policy-actions/; https://www.bestcolleges.com/news/2021/10/11/list-of-colleges-that-require-covid-19-vaccine/#:~:text=A%20still%2Dexpanding%20group%20of,and%20public%2C%20have%20followed%20suit; https://www.nashp.org/states-enact-policies-to-support-students-transition-back-to-school/; https://news.bloomberglaw.com/daily-labor-report/vaccine-mandates-at-work-part-of-new-normal-employers-say; https://ny.eater.com/2022/3/9/22967384/nyc-restaurants-bars-proof-of-vaccination-requirement (last accessed July 14, 2022).

[36] *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).

[37] *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).

[38] *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).

[39] *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.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-

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.

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 FDA'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, and whether to politically support vaccine mandates and passports—has an urgent need to understand how the FDA, a federal government agency, has followed through on its promise to vigilantly monitor the safety of COVID-19 vaccines. The public has an urgent need to know what safety signals the FDA has uncovered and how those signals have been investigated. The public has an urgent need to understand how the FDA continues to reach its conclusion that the COVID-19 vaccines are safe.

A lack of transparency about how FDA has made good on its promises of safety monitoring both deprives people of the information needed to make fully informed medical and political decisions, and erodes confidence in the conclusions reached and guidance promulgated by the federal government and its agencies.

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

Note that if only portions of a requested file are exempted from release, the remainder must still be released. We, therefore, request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies.

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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).

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.

As indicated above, we are applying for expedited processing of this Request. 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.

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

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 2

U.S. FOOD & DRUG ADMINISTRATION

August 02, 2022

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

In Reply refer to
FOIA Control #:
2022-5587

Requester reference:

Dear Requester:

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

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

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

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

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

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

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

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

and/or

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

Sincerely,

SARAH KOTLER
Director

EXHIBIT 3

U.S. FOOD & DRUG ADMINISTRATION

August 08, 2022

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

In Reply refer to
FOIA Control #:
2022-5587

Requester reference:

Dear Requester:

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

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

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

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

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

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

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

Sincerely,

SARAH KOTLER
Director

EXHIBIT 4

Correspondence for First FOIA Request and Appeal of First FOIA Request

Gmail **Risa Evans** [redacted]>

Follow up regarding request #2022-5587

Risa Evans [redacted]> Wed, Sep 7, 2022 at 2:47 PM
To: elizabeth.sly@fda.hhs.gov
Bcc: Risa Evans <[redacted]>

Hi Elizabeth
Thank you for your time and guidance during our phone conversation yesterday, as well as during the conversation we had on August 26. I'm writing to confirm that I understand correctly where things stand with the FOIA request, and also to narrow the request in the way we discussed.

First, confirming that on the 26th, we narrowed the request by eliminating item 1, because the CDC, not the FDA, is the custodian of the Daily Priority Reports requested in that item.

Second, from what we di cu ed, I under tand that CBER will likely recommend "deliberative proce " e emption for items 2, 3, 4, and 5 of the request. However, the FDA will not provide a final determination before the request for records in item 6 is processed, which will likely take 3-6 months. Because I would like to be able to appeal the determination as quickly as possible, I would like to narrow the request by removing item 6; hopefully this narrowing will keep the determination moving at a better pace

Thank you again for your help!
Risa

Gmail

Risa Evans <[redacted]>

FW: Request Number: 2022-5587

Kotler, Sarah <Sarah.Kotler@fda.hhs.gov> Tue, Oct 4, 2022 at 11:10 AM
To: Risa Evans <[redacted]>

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information

US FDA

301-796-8976

From Kotler, Sarah
Sent: Tuesday, October 4, 2022 11:02 AM
To: risa.evans@childrenshealthdefense.org
Subject: Request Number: 2022-5587

October 4, 2022

Request Number: 2022-5587

Dear Requester:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA) for "Record of the daily email alert /Daily Priority Report received by FDA and/or CBER from CDC's VAERS contractor, including but not limited to any lists of VAERS ID numbers for reports of adverse events of special interest (AESIs) after COVID-19 vaccines;10 2) Records of any manual review of serious ASEI reports conducted by FDA and/or CBER etc."

You agreed to withdraw items 1 and 6 of your request. We are denying items 2, 3, 4, and 5.

The following exemption(s) of FOIA, 5 U.S.C. 552, is the authority for denying you access to the non-disclosable material E emption (b)5 Certain interagency and intra agency communication We have included citation to the FOIA and FDA's regulations for your information.

Section 5.31 (e) of the implementing regulations of the Department of Health and Human Services (DHHS) is applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

The following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21

- Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative proce of FDA, from which factual information i not rea onably egregable The information al o contains a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges as enunciated by the Supreme Court in National Labor Relations Board v. Sears, Roebuck & Co., 421 U.S. 132 (1975) of the implementing regulations of FDA and reason(s) applicable to this denial

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and recon ider your reque t and the agency' deci ion Your appeal mu t be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to di cu our re pon e before filing an appeal to attempt to re olve your di pute without going through the appeals process, please contact Sarah Kotler at 301-796-8976. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA reque ter and Federal agencie The contact information for OGIS i a follow Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

Sincerely yours,

Sarah Kotler

Director

Division of Freedom of Information

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information

US FDA

301-796-8976

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FDA Freedom of Information Act Appeal

FDA FOIA <FDAFOIA@fda.hhs.gov> Wed, Oct 12, 2022 at 10:41 AM
To: CHD FOIA <foia@childrenshealthdefense.org>, FDA FOIA <FDAFOIA@fda.hhs.gov>

Appeal file: 22-000123AA

October 12, 2022

Sending via Email: risa.evans@childrenshealthdefense.org

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, submitted to the Food and Drug Administration (FDA). We received your appeal on October 12, 2022. Your appeal challenges the *Food and Drug Administration (FDA's)* response to your original request ***#2022-5587***. Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Your appeal is summarized below:

Denied Records

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal. For more information about how your appeal will be processed please refer to the HHS FOIA regulations https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

The FOIA and the HHS FOIA regulations are available at the following web addresses: https://www.justice.gov/oip/freedom-information-act-5-usc-552 and https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations.

If you have any questions, please call (301)796 8975, or email us at fdafoia@fda hhs gov

Sincerely yours,

Sarah Kotler

FDA FOIA

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information

US FDA

301-796-8976

From: CHD FOIA <foia@childrenshealthdefense.org>
Sent: Tuesday, October 11, 2022 11:46 AM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Subject: [EXTERNAL] FDA Freedom of Information Act Appeal

[Quoted text hidden]

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

Status of Appeal #22-000123AA

CHD FOIA <foia@childrenshealthdefense.org> Fri, Nov 18, 2022 at 3:08 PM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Cc: CHD FOIA <foia@childrenshealthdefense.org>

Hello,
Would you kindly let me know when we can expect a ruling of appeal #22-000123AA, which was filed on October 12, 2022.
Thank you.
Sincerely,
Risa Evans, for
Children's Health Defense

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

Status of Appeal #22-000123AA

FDA FOIA <FDAFOIA@fda.hhs.gov> Mon, Nov 21, 2022 at 7:43 AM
To: CHD FOIA <foia@childrenshealthdefense.org>, FDA FOIA <FDAFOIA@fda.hhs.gov>

Hi, the appeals process is about 9-12 months. I would expect you will get a final response around the summer of 2023.

Thanks,

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information

US FDA

301-796-8976

From CHD FOIA foia@children healthdefen e org
Sent: Friday, November 18, 2022 3:09 PM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Cc: CHD FOIA <foia@childrenshealthdefense.org>
Subject [E TERNAL] Statu of Appeal #22 000123AA

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

[Quoted text hidden]

Correspondence for Second FOIA Request

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA #2022-6498

CHD FOIA <foia@childrenshealthdefense.org> Wed, Oct 12, 2022 at 10:56 AM
To: wilson.russ@fda.hhs.gov

Hello,

I'm writing in connection with FOIA 2022-6498, which was filed on September 8, 2022. Would FDA please provide us with a final determination on the request, or else provide a date by which we can expect such determination?

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

PS Please note that the original FOIA was filed from my personal gmail address during a time when FDA was not accepting emails from Children's Health Defense. Thanks to your assistance, that problem was solved, so we would like to switch correspondence about FOIA 2022-6498 to this CHD FOIA email address. Thanks again for your assistance in re olving the email i ue!

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA #2022-6498

Russ, Wilson <Wilson.Russ@fda.hhs.gov> Wed, Oct 12, 2022 at 11:02 AM
To: CHD FOIA <foia@childrenshealthdefense.org>

Good afternoon,

Your request is still pending with the Center for Biologics Evaluation Research (CBER). At this time I do not have any updates. You may contact their FOIA Line at 240-402-8008 or email Beth Brockner-Ryan at beth brocknerryan@fda hh gov to get a better timeframe of completion

Thank you,

Wil on M Ru

Government Information Specialist

Office of the Executive Secretariat

Division of Freedom of Information

U S Food and Drug Administration

Tel 301 796 8981

wilson russ@fda hhs gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: CHD FOIA <foia@childrenshealthdefense.org>
Sent Wedne day, October 12, 2022 10 57 AM
To: Russ, Wilson <Wilson.Russ@fda.hhs.gov>
Subject: [EXTERNAL] FOIA #2022-6498

[Quoted text hidden]

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA #2022-6498

CHD FOIA <foia@childrenshealthdefense.org> Wed, Oct 12, 2022 at 11:54 AM
To: beth.brocknerryan@fda.hhs.gov

Hello,

I'm writing in connection with FOIA 2022-6498, which was filed on September 8, 2022. Would you please provide us with a final determination on the request, or else a date by which we can expect such determination?

Thank you!

Sincerely,
Risa Evans, for
Children' Health Defen e

Children's Health Defense

CHD FOIA <foia@childrenshealthdefense.org>

FOIA #2022-6498

CHD FOIA <foia@childrenshealthdefense.org> Mon, Nov 21, 2022 at 4:29 PM
To: beth.brocknerryan@fda.hhs.gov

Hello,
I'm writing to follow up on my email of October 12, 2022 in connection with FOIA 2022 6498, which wa filed on September 8, 2022.
Would you kindly provide us with a final determination on the request.
Thank you.
Ri a Evan , for
CHD
[Quoted text hidden]

EXHIBIT 5

October 11, 2022

FDA FOIA APPEALS OFFICE
FDAFOIA@fda.hhs.gov

Re: Appeal of FOIA Request #2022-5587

To Whom it May Concern:

This is an administrative appeal of the Food and Drug Administration's (FDA) final response to FOIA request #22-5587. Children's Health Defense (CHD) respectfully requests your assistance in obtaining the FDA's full compliance with the Freedom of Information Act in connection with this request. Specifically, FDA should do the following:

(1) immediately search for responsive records;
(2) promptly provide all non-exempt records to CHD;
(3) for any material alleged to be exempt, describe the withheld or redacted material, the context for the material, and the claimed exemption in sufficient detail to demonstrate how and why the exemption applies; and
(4) for any non-exempt material that is not disclosed, explain why it is not reasonably segregable from exempt material.

I. Procedural Background

The February 2021 "VAERS Monitoring Standard Operating Procedure" (VAERS SOP) describes the specific methods the FDA and the Centers for Disease Control (CDC) have promised to use on an ongoing basis to monitor the Vaccine Adverse Events Reporting System for safety signals in connection with COVID-19 vaccines. The SOP is available to the public on the CDC's website.[1]

On July 27, 2022, CHD submitted a FOIA request seeking records of safety monitoring conducted by the FDA pursuant to the VAERS SOP. *See Addendum 1, Request*. The request seeks six items, as follows:

[1] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf (last accessed October 8, 2022).

1) Records of the daily email alerts/Daily Priority Reports received by FDA and/or CBER from CDC's VAERS contractor, including but not limited to any lists of VAERS ID numbers for reports of adverse events of special interest (AESIs) after COVID-19 vaccines;[2]
2) Records of any manual review of serious ASEI reports conducted by FDA and/or CBER;[3]
3) Records of any Empirical Bayesian data mining conducted by FDA and/or CBER, and records of any sharing or discussion of results and signals with the CDC;[4]
4) Records of any results and signals received by FDA and/or CBER from the CDC's own PRR data mining, and any discussion of those results;[5]
5) Records of any consultations by FDA and/or CBER with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected detected.[6]
6) Records of the Empirical Bayesian data mining conducted on or about November 17, 2021, as described in "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021."

After communication with the FOIA office at the Center for Biologics Evaluation and Research (CBER), CHD withdrew two items. Item (1) was withdrawn because CBER indicated the daily email alerts are in the custody of the CDC, not the FDA. Item (6) was withdrawn when CBER indicated that the search for records responsive to item (6) would delay the FDA's response on items (2) through (5) because the FDA does not issue partial responses to FOIA requests. CHD filed a new request for the records described in Item 6; this is assigned FOIA #2022-6498 and is currently being processed.

On October 4, 2022, the FDA provided a final response, denying items 2, 3, 4, and 5. The response alleges a blanket exemption under 5 U.S.C. §552(b)(5) and associated Department of Health and Human Services regulations. *See Addendum 2, Final Response*.

The final response claims the denial is authorized for two reasons: (1) because the requested records are "[i]ntra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable," and (2) because "the information also contains a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges as enunciated by the Supreme court…" *See id*.

[2] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf. at p. 12.
[3] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 12.
[4] *I*https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17.
[5] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at p. 17.
[6] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 16-17, 19.

II. Legal Background

When a federal agency like the FDA receives a properly formulated FOIA request, the Freedom of Information Act requires the agency to search for records responsive to the request, and promptly make those records available. *See* 5 U.S.C. § 552(a)(3)(A)-(D)

If any portion of the records is exempt, the agency must consider whether partial disclosure of the information is possible, and "take reasonable steps necessary to segregate and release nonexempt information." *See id*. at § 552 (a)(8)(A)(i) and (ii).

A) Deliberative process exemption

The "deliberative process" exemption available under 5 U.S.C. § 552 (b)(5) is designed to protect the decision-making processes of government agencies. *National Labor Relations Board v. Sears, Roebuck & Co*., 421 U.S. 132, 150 (1975). It protects from disclosure "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *Electronic Frontier Foundation v. U.S. Dept. of Justice*, 826 F. Supp. 2d 157, 165 (D.D.C. 2011) *(*quoting *Sears*, 421 U.S. at 150) (internal quotation marks omitted).

The exemption may be invoked by an Agency only where (1) a communication is pre-decisional, that is, "antecedent to the adoption of an agency policy," and (2) the communication is deliberative, that is, a "direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters." *Vaughn v. Rosen*, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975).

Exemption 5 "does not authorize an agency to throw a protective blanket over all information." *American Radio Relay League Inc. v. FCC*, 524 F.3d 227 238 (D.C. Cir. 2008). Rather, the Agency has the burden of showing the non-disclosed information falls within the claimed exemption. *Electronic Frontier Foundation*, 826 F. Supp. 2d at 163-64. In this context, "conclusory and generalized allegations of exemptions are unacceptable." *Id*. at 164 (internal quotations and citation omitted).

While the Agency need not identify a specific agency decision to meet its burden of showing that a record is "pre-decisional," the Agency must at least describe the "nature of the deliberative process involved and the function and significance of the document in that process." *See Public Employees for Environmental Responsibility v. EPA*, 213 F. Supp. 3d 1, 13 (D.D.C. 2016). It must also provide the "nature of the decisionmaking authority vested in the document's author and recipient." *Id*. at 18.

The need to describe "*each withheld document* when Exemption 5 is at issue is particularly acute because the deliberative process privilege is so dependent upon the individual document and the role it plays in the administrative process." *Electronic Frontier Foundation,* 826 F. Supp. 2d at 167-8 (emphasis added; internal quotations and citation omitted). Moreover, the Agency must describe "not only the contents of the

document but also enough about its context. . .to establish that it is a pre-decisional part thereof." *Id*. at 168 (internal quotation and citation omitted).

Notably, exemption 5 applies "only to the *deliberative* portion of a document and not to any purely factual, non-exempt information the document contains." *Army Times Pub. Co. v. Department of Air Force*, 998 F.2d 1067, 1070 (D.C. Cir. 1993) (emphasis added); s*ee also EPA v. Mink*, 410 U.S. 73, 91 (1973). Non-exempt information must be disclosed if it is "reasonably segregable" from exempt portions of the record. *Army Times* 998 F.2d at 1070.

B) Attorney-client and work-product privilege

When claiming attorney-client privilege under 5 U.S.C. § 552 (b)(5), the Agency bears the burden of proving, through "detailed and specific information," that the withheld information falls within the attorney-client privilege. See Campbell v. U.S. Dep't of Justice, 164 F.3d 20, 30 (D.C. Cir. 1998).

Additionally, the work-product privilege ordinarily does not attach until at least "some articulable claim, likely to lead to litigation" has arisen. Coastal States, 617 F.2d at 865.

III. The Insufficiency of the FDA's Final Response

With its generic and conclusory allegations of exemption, the FDA's final response to FOIA Request #2022-5587 does not comply with FOIA requirements.

The FDA has not indicated that FOIA Request #2022-5587 is anything other than a properly formulated FOIA request. However, the FDA's response does not indicate that FDA has searched for any of the requested records. Indeed, the response does not even indicate whether the requested records exist.

To the extent the records do exist, the response does not provide any information about the number of type of records or the authors of the records.

To the extent the records do exist, the response does not provide any information about the context of the records, the nature of the deliberative process underlying the claimed exemption, or the role played by the records in that process.

To the extent the records do exist, the response does not provide any information to support a claim of attorney-client or work-product privilege.

To the extent the records exist and contain some information that is exempt from disclosure, the response does not indicate why it is not possible to segregate and disclose the non-exempt information.

IV. Requested relief

CHD respectfully requests your assistance with obtaining FDA's full compliance with its obligations under the FOIA. Specifically, the FDA should:

(1) immediately search for responsive records;
(2) promptly provide all non-exempt records to CHD;
(3) for any material alleged to be exempt, describe the withheld or redacted material, the context for the material, and the claimed exemption in sufficient detail to demonstrate how and why the exemption applies; and
4) for any non-exempt material that is not disclosed, explain why it is not reasonably segregable from exempt material.

As to the timing of actual production of the requested records, FDA must make the records "promptly available." *See* 5 U.S.C. § 552(a)(3)(A)(a)(6)(C)(i). Depending on the circumstances, this "typically would mean within days or a few weeks of a "determination," not months or years." *See Citizens for Responsibility and Ethics in Washington v. Federal Election Com'n*, 711 F.3d 180, 188 (D.C. Circ. 2013).

CHD respectfully requests that your office issue a directive to the FDA to complete the actions described above and provide us with the requested records within 20 days. As noted in a recent opinion regarding the timing of the FDA's disclosure of records in connection with Pfizer's COVID-19 vaccine, "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Public Health & Medical Professionals for Transparency v. FDA*, No. 4:21-cv-1058-P (N.D. Texas, slip op., Jan. 6, 2022) (internal quotations and citations omitted). Indeed, "[S]tale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988).

We would like to settle this matter without court intervention if possible. If you wish to discuss this appeal, please do not hesitate to contact me at foia@childrenshealthdefense.org.

Thank you for your consideration.

Sincerely,
/s/ *Risa Evans*
Risa Evans, Senior Legal Fellow, for
Children's Health Defense
foia@childrenshealthdefense.org

ADDENDA OMITTED

EXHIBIT 6

Children's Health Defense

September 8, 2022

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

Submitted via FDA's ONLINE FOIA PORTAL

Re: Freedom of Information Act Request for records of data underlying the article, "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination"

Dear Sir or Madam:

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

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R Part 5, Children's Health Defense (CHD) requests records of the Empirical Bayesian data mining described on pages 9-10 of the article, "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021."[1]

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

[1] https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.full.pdf.

Guidance Regarding the Search and Processing of Requested Records

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

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

- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,[2] and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in PST files, outside of network drives, in paper format, or in personal email accounts.

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

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

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

- 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.

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[2] 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.

Fee Waiver Request

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

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

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

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

CHD uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. The organization also makes materials it gathers available on its public website[4] and newsletter and promotes their availability on social media platforms, such as Twitter.[5]

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.[6]

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

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

Conclusion

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

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

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

Thank you for your time and attention to this matter.

Sincerely yours,

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

EXHIBIT 7

U.S. FOOD & DRUG ADMINISTRATION

September 09, 2022

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

In Reply refer to
FOIA Control #:
2022-6498

Requester reference:

Dear Requester:

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

records of the Empirical Bayesian data mining described on pages 9-10 of the article, "Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021."

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

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

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

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

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

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

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director