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;

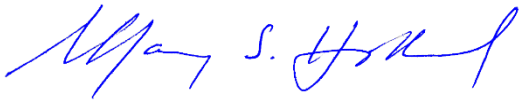
(E) Enjoin FDA from continuing to withhold non-exempt records responsive to CHD's FOIA requests;

(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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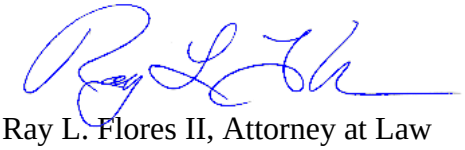

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