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

1. This Complaint concerns a Freedom of Information Act (FOIA) request Children's Health Defense (CHD) submitted to the U.S. Food and Drug Administration (FDA) in September 2022 seeking records of the FDA's monitoring of "adverse events of special interest" (AESIs) in connection with COVID-19 injections. To date, the FDA has not provided a response to the request. CHD now brings this action to compel compliance with FOIA, 5 U.S.C. § 552 ("FOIA").

PARTIES

2. Plaintiff Children's Health Defense (CHD) is a California nonprofit corporation with a mailing address of 852 Franklin Ave., Suite 511, Franklin Lakes, New Jersey 07417.

3. CHD works to end childhood and other health epidemics by eliminating harmful exposures, holding those responsible accountable, and establishing safeguards to prevent future harm. CHD also fights corruption, mass surveillance and censorship that put profits before

people as well as advocating for worldwide rights to health freedom and bodily autonomy. CHD is also committed to educating the general public in connection with these efforts.[1] As part of its work, CHD regularly requests records from federal agencies pursuant to FOIA.

4. Defendant Food and Drug Administration (FDA), headquartered at 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993, is an agency within the executive branch of the United States Government under 5 U.S.C. § 552(f). FDA has possession, custody, and control of records to which Plaintiff seeks access.

JURISDICTION AND VENUE

5. 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 Request

6. The U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations for various COVID-19 vaccines beginning in December 2020.

7. The Federal Government has touted COVID-19 vaccination as "safe and effective,"[2] and to help ensure broad COVID-19 vaccine acceptance and uptake, has assured the public that U.S. public health agencies are vigilantly monitoring the COVID-19 vaccine for safety. For example, 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.

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

[2] *See, e.g.*, *Safety of COVID-19 Vaccines*, CENTERS FOR DISEASE CONTROL AND PREVENTION (updated Mar. 7, 2023), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last accessed August 2, 2023).

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."[3] (Emphasis added.)

8. The FDA's COVID-19 Vaccine Surveillance webpage lists several types of COVID-19 vaccine surveillance,[4] including surveillance dubbed the "BEST Initiative" (Biologics Effectiveness and Safety), which is more fully described in the Center for Biologics Evaluation and Research's (CBER) "COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol" ("*BEST Protocol*").[5]

9. The goal of the BEST Initiative is to "monitor the rates of various adverse events of special interest (AESIs) following COVID-19 vaccination in near real-time following authorization or licensure."[6]

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[3] *See 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 (emphasis added) (last accessed July 24, 2023); *see also Safety of COVID-19 Vaccines*, *supra*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.

[4] *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.

[5] See *CBER Surveillance Program, COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol*, U.S. Food & Drug Administration Center for Biologics Evaluation and Research Office of Biostatistics and Epidemiology, BESTINITIATIVE.ORG (Feb. 10, 2021), https://bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-Protocol-2021.pdf (last accessed July 24, 2023).

[6] *See id*. at p. 6.

10. Addenda to the *BEST Protocol* ("*BEST Protocol Addenda*") describe similar adverse event monitoring and analysis with respect to COVID-19 booster shots,[7] and COVID-19 vaccines for children.[8]

B. CHD's FOIA Request

11. On September 7, 2022, CHD submitted a FOIA request to the FDA seeking records in connection with the safety-monitoring conducted by FDA under the *BEST Protocol*. *See* Ex. 1, FOIA Request.

12. The FOIA request sought the following records generated in connection with the *BEST Protocol* and the *BEST Protocol Addenda* for each (a) data source studied, (b) COVID-19 vaccine brand studied, (c) age group studied, and (d) AESI studied:

A) Descriptive summaries of observed rates of AESIs, described in section 4.5 on pages 12-13 of the *BEST Protocol*;

B) Records of the sequential analyses of AESIs described in section 4.6 on pages 13-24 of the *BEST Protocol* (including both PMaxSPRT and BMaxSPRT);

C) Records of any discrepancies discovered through the quality assurance described in section 4.7 on page 24 of the *BEST Protocol*, and of any follow-up investigation conducted into those discrepancies;

D) For any safety signal that was detected, records of any signal verification that was conducted as described in section 4.8 on pages 24-26 of the *BEST Protocol*.

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[7] *See ADDENDUM, COVID-19 Vaccine Safety Surveillance: Active Monitoring Protocol, CBER Surveillance Program, Biologics Effectiveness and Safety Initiative* (*BEST*), Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV), BESTINITIATIVE.ORG (May 27, 2022), https://bestinitiative.org/wp-content/uploads/2022/06/C19-Booster-Active-Monitoring-Protocol-Addendum-2022.pdf (Addendum describing monitoring in connection with third or booster dose administration among adults ages 18 and older).

[8] *See ADDENDUM, COVID-19 Vaccine Safety Surveillance: Active Monitoring Protocol Addendum, CBER Surveillance Program, Biologics Effectiveness and Safety Initiative (BEST)*, Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV), BESTINITIATIVE.ORG (Apr. 12, 2022), https://bestinitiative.org/wp-content/uploads/2022/04/C19-Active-Monitoring-Protocol-Addendum-2022.pdf (Addendum describing monitoring of AESIs among children between ages of 5 and 17 years) (last visited July 24, 2023).

13. The request sought a fee waiver. *See id*. Additionally, the request sought expedited processing, noting the Federal Government's ongoing efforts to promote COVID-19 vaccination, the limited safety-data available from the clinical trials, the ongoing public weighing of the risks and benefits of the injections, and the ongoing public debate about vaccination policy. *See id*. The request argued, "The public has an urgent need to understand how the FDA, a Federal Government agency, has followed through on its promise to vigilantly monitor the safety of COVID-19 vaccines. The public has an urgent need to know what safety signals the FDA has uncovered and how those signals have been investigated. The public has an urgent need to understand how the FDA continues to reach its conclusion that the COVID-19 vaccines are safe." *See id*.

14. On September 9, 2022, the FDA acknowledged the request, assigning it #2022-6494. The acknowledgment indicated "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." *See* Ex. 2, Acknowledgment. The acknowledgment did not indicate that the FOIA request is unclear, overbroad, or otherwise improperly formulated. *See id.* On September 14, 2022, FDA denied CHD's request for expedited processing. *See* Ex. 3, Denial of Expedited Processing.

15. On October 12, 2022, CHD emailed FDA requesting a final determination, or else a date certain by which a final determination will be forthcoming. FDA did not respond to the email. *See* Ex. 4, Correspondence.

16. On November 18, 2022, CHD sent a follow-up email to FDA, requesting the same. *See* Ex. 4, Correspondence. FDA did not respond to the email.

17. On May 11, 2023, CHD communicated with a FOIA "point of contact" at CBER, who indicated that the request is clear and requires no further clarification. The point of contact

indicated the request is in the FDA's "complex" queue and would not be assigned for processing for at least twenty-four months. *See* Ex. 4, Correspondence.

18. To date, FDA has not provided a final determination or any records.

COUNT I

VIOLATION OF FOIA, 5 U.S.C. § 552

19. The previous allegations are incorporated by reference as if fully set forth herein.

20. 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).

21. 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); 5 U.S.C. § 552(a)(6)(E) (providing for expedited processing upon showing of compelling need).

22. FDA has violated the FOIA through its failure to provide a final determination, and failure to provide any of the records to which CHD is entitled under law.

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 CHD's FOIA 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: August 10, 2023

Respectfully submitted,

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