UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK, 2025 Guadalupe Street, Suite 260 Austin, Texas 78705 Plaintiff, -against- FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Ave Silver Spring, MD 20993-0002 Defendant.	Civil Action No. 1:23-cv-1508

COMPLAINT

Plaintiff Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") brings this action against Defendant Food and Drug Administration ("**FDA**" or "**Defendant**") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("**FOIA**"). As grounds therefor, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705.

4. Defendant FDA is an agency within the Executive Branch of the United States Government, organized within the U.S. Department of Health and Human Services. FDA is an

agency within the meaning of 5 U.S.C. § 552(f). FDA has possession, custody, and control of records to which Plaintiff seeks access.

STATEMENT OF FACTS

5. Plaintiff discovered VAERS reports concerning minors who reportedly died or suffered severe adverse reactions shortly after receiving a COVID-19 vaccine, or after exposure to breastmilk from a woman who had received a COVID-19 vaccine, prior to any COVID-19 vaccine being authorized, approved, or recommended by federal health authorities for use by minors. Therefore, Plaintiff submitted the instant FOIA requests to understand what, and when, federal health authorities knew about COVID-19 vaccine-related deaths or adverse events in minors in relation to the health authorities' authorization and/or recommendation of the widespread use of the vaccines in the pediatric population.

6. FDA received four FOIA requests submitted by Plaintiff between April 27 and May 11, 2021. On April 27, 2021, FDA acknowledged its receipt of the first request which sought the following records:

> All documents concerning VAERS Report No. 1074247.

(**Exhibit 101** at 19.)

7. On April 27, 2021, FDA also acknowledged its receipt of the second request which sought the following records:

> All documents concerning VAERS Report Nos. 1099241-1 and 1166062-1.

(**Exhibit 101** at 36.)

8. On May 4, 2021, FDA acknowledged its receipt of the third request which sought the following records:

> All documents concerning the following VAERS Report Nos.: 1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 1243516.

(Exhibit 101 at 46.)

9. On May 12, 2021, FDA acknowledged its receipt of the fourth request which sought the following records:

> All documents concerning the following VAERS Report Nos.: 1255745 and 1261766.

(**Exhibit 101** at 56.)

10. Between May 21 and June 11, 2021, FDA issued final response letters for the four FOIA requests. In each final response letter, FDA established the following references numbers for each request, respectively: 21-2759, 21-2761, 21-2954, 21-3130. For reach request, FDA also stated that it produced certain responsive records and withheld certain responsive records under FOIA Exemptions 3 and 6. (**Exhibit 101** at 24, 40, 48, 58.)

11. On August 19, 2021, Plaintiff filed a joint appeal concerning the final responses for the four FOIA requests challenging the adequacy of FDA's search and its justifications for withholding records under Exemptions 3 and 6. (**Exhibit 101**.)

12. FDA Denials and Appeals Officer, Katherine Uhl, notified Plaintiff via email on November 15, 2021 of the agency's determination with respect to Plaintiff's joint appeal. FDA determined "the actions necessary to complete [Plaintiff's] initial request[s] are yet to be accomplished" and it was "remanding these requests back to the FDA for completion." Furthermore, the notification stated that "[t]his action will close [Plaintiff's] appeal and allow the necessary, remaining processes to take place in response to [Plaintiff's] initial request. We will, however, monitor the progress of this request." (**Exhibit 102** at 2.)

13. After November 19, 2021, Plaintiff did not receive any further correspondence regarding the status of the remanded requests. Therefore, on January 23, 2023, Plaintiff emailed FDA inquiring about status of the remanded requests. (*See* **Exhibit 102** & **103**.)

14. On February 2, 2023, Charis Wilson, a Denials and Appeals Officer for FDA, responded to Plaintiff's inquiry, stating in relevant part:

> Additional searches were performed for all four requests after they were remanded back to CBER.
> - For FOIA #s 2021-2759, 2021-2761 and 2021-3130---estimated date of completion is 6 months from now.
> - For FOIA # 2021-2954---estimated date of completion is 18-24 months from now.

(**Exhibit 103**.)

15. In the more than ninety (90) days since, Defendant has neither produced any further responsive documents nor made anygood faith attempts to discuss with Plaintiff how it could effectively limit the scope of the requests.

16. Despite the passage of nearly a year and a half since the four requests had been remanded back to FDA for its failure to perform the necessary actions to complete the requests, as of the date of this Complaint, FDA has failed to: (i) determine whether to comply with the requests; (ii) notify Plaintiff of any such determination or the reasons therefor; (iii) advise Plaintiff of the right to appeal any adverse determination; or (iv) produce the requested records or otherwise demonstrate that the requested records are exempt from production.

17. Thus, Defendant has failed to abide by the time limits prescribed by FOIA.

COUNT I
FAILURE TO MAKE DETERMINATION BY REQUIRED DEADLINE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

18. Plaintiff realleges paragraphs 1 through 18 as if fully stated herein.

19. Defendant is in violation of FOIA.

20. Defendant was required to make a final determination on Plaintiff's requests no later than December 13, 2021. Because Defendant failed to make a final determination on Plaintiff's requests within the time limits set by FOIA, Plaintiff is deemed to have exhausted its administrative appeal remedies.

21. Defendant made no good faith attempts to discuss with Plaintiff how it could effectively limit the scope of the requests.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Declare that Defendant's current and continued delay in processing Plaintiff's FOIA requests is unlawful under FOIA;

b. Order Defendant to conduct and complete searches for any and all records responsive to Plaintiff's FOIA requests and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA requests;

c. Order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA requests and a *Vaughn* index of any responsive records withheld under any claimed exemption;

d. Enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA requests;

e. Enjoin Defendant from charging any fees for the FOIA requests since the agency failed to comply with time limits under FOIA;

f. Maintain jurisdiction over this action until Defendant complies with FOIA and all orders of this Court;

g. Grant Plaintiff 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

h. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: May 25, 2023

SIRI & GLIMSTAD LLP

/s/ Elizabeth Brehm

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