

**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 Avenue
Silver Spring, MD 20993-0002

-and-

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
200 Independence Avenue S.W.
Washington, DC 20201

Defendants.

Civil Action No. 1:25-cv-825

COMPLAINT

Plaintiff Informed Consent Action Network (“**ICAN**” or “**Plaintiff**”) brings this action against defendants Food and Drug Administration (“**FDA**”) and the United States Department of Health and Human Services (“**HHS**”) (collectively “**Defendants**”) to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 (“**FOIA**”). As grounds therefore, 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 5 U.S.C. § 522(a)(4)(B) and 28 U.S.C. § 1331.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization formed and existing under the laws of the state of Texas, with its principal office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705. Plaintiff is in good standing with the Texas Secretary of State.

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.

5. Defendant HHS is an agency within the Executive Branch of the United States Government. HHS is an agency within the meaning of 5 U.S.C. § 552(f) and has possession, custody, and control of records to which Plaintiff seeks access.

STATEMENT OF FACTS

6. On January 26, 2024, Plaintiff sent a FOIA request to FDA seeking copies of the following records:

The final study reports for the following studies:

- (1) C4591001: Deferred pediatric study to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age;
- (2) C4591014: Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California; and
- (3) C4591031: Sub-study incidence to prospectively of subclinical myocarditis assess the following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

Information Helpful to Fulfilling the Request: The three studies are Commitments 1, 9, and 13 of the postmarket requirements for the Pfizer-BioNTech COVID-19 vaccine, attached hereto as Attachment A.

(Exhibit 1.)

7. Defendant FDA acknowledged Plaintiff's FOIA request on January 29, 2024, and assigned the request FOIA number 2024-965. (**Exhibit 2.**)

8. As of the date of this Complaint, Defendants have failed to: (i) determine whether to comply with the request as required under 5 U.S.C. § 552(6)(A)(i); (ii) notify Plaintiff of any such determination or the reasons therefor as required under § 552 (6)(A)(i)(I); (iii) advise Plaintiff of the right to appeal any adverse determination not to comply with the request, as required under § 552(6)(A)(i)(III)(aa); or (iv) produce the requested records or otherwise demonstrate that the requested records are exempt from disclosure pursuant to § 552(b).

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

9. Plaintiff realleges the previous paragraphs as if fully stated herein.

10. Defendants are in violation of FOIA.

11. 5 U.S.C. § 552(a)(6)(A)(i) requires Defendants to make a final determination on Plaintiff's request no later than twenty (20) business days from acknowledgement of the request. Because Defendants failed to make a final determination on Plaintiff's request within the time limits set by FOIA, under § 552(6)(C)(i) Plaintiff is deemed to have exhausted its administrative appeal remedies.

12. Plaintiff is being irreparably harmed because of Defendants' violation of FOIA and Plaintiff will continue to be irreparably harmed unless Defendants are compelled to comply with the law.

13. Plaintiff has no adequate remedy at law.

COUNT II
FAILURE TO PROVIDE AN ESTIMATED COMPLETION DATE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

- 14. Plaintiff realleges the previous paragraphs as if fully stated herein.
- 15. Defendants are in violation of FOIA.
- 16. The agency never provided an estimated date of completion.

COUNT III
IMPROPER WITHHOLDING OF INFORMATION AND DATA
(VIOLATION OF FOIA, 5 U.S.C. § 552)

- 17. Plaintiff realleges the previous paragraphs as if fully stated herein.
- 18. Defendants have failed to establish that they adequately applied an exemption to—
or withheld—any responsive records.
- 19. Defendants are in violation of FOIA.

COUNT IV
FAILURE TO ESTABLISH AN ADEQUATE SEARCH
(VIOLATION OF FOIA, 5 U.S.C. § 552)

- 20. Plaintiff realleges the previous paragraphs as if fully stated herein.
- 21. Defendants have failed to establish that they adequately searched for responsive
records as required by 5 U.S.C. § 552 (a)(3)(C) and (D).
- 22. Defendants are in violation of FOIA.

COUNT V
ENTITLEMENT TO WAIVER OF SEARCH AND DUPLICATION FEES

- 23. Plaintiff realleges the previous paragraphs as if fully stated herein.
- 24. Defendants are in violation of FOIA.
- 25. Plaintiff sought a waiver of search and duplication fees pursuant to 5 U.S.C. §
552(a)(4)(A)(ii)(II).

26. Plaintiff is further entitled to a waiver of fees pursuant to 5 U.S.C. § 552(a)(4)(A)(viii) because Defendants failed, within 20 days, to produce the requested records and otherwise failed to comply with the statutory requirements of 5 U.S.C. § 522 within the time limits set forth therein.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

- a. Declare that Defendants' current and continued delay in processing Plaintiff's FOIA Request is unlawful under FOIA;
- b. Order Defendants to conduct searches for any and all records responsive to Plaintiff's FOIA request and demonstrate that they employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA request;
- c. Order Defendants to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA request and a *Vaughn* index of any responsive records withheld under any claimed exemption;
- d. Enjoin Defendants from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA request;
- e. Maintain jurisdiction over this action pursuant to 552(a)(6)(C)(i) until Defendants comply with FOIA and all orders of this Court;
- f. 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);
- g. Grant Plaintiff a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A)(viii); and

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

Dated: March 19, 202

SIRI & GLIMSTAD LLP

/s/Mark Taylor

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