GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
By: SAMUEL DOLINGER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2677
E-mail: samuel.dolinger@usdoj.gov

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -v- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	20 Civ. 689 (AJN) **ANSWER TO AMENDED COMPLAINT**

Defendant the United States Food and Drug Administration ("FDA" or "Defendant"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, hereby answers the amended complaint under the Freedom of Information Act ("FOIA") of Informed Consent Action Network ("ICAN" or "Plaintiff") upon information and belief as follows:

1. The first two sentences of Paragraph 1 contain legal conclusions and characterizations of statutory provisions, to which no response is required. FDA respectfully refers the Court to the relevant statutory provisions for a complete and accurate statement of their contents. FDA admits the allegations in the third sentence of Paragraph 1, and avers that FDA and the Centers for Disease Control and Prevention ("CDC") are agencies within the Department of Health and Human Services ("HHS").

2. The allegations in Paragraph 2 consist of legal conclusions to which no response is required.

3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, except admits that in June 2019, ICAN submitted a FOIA request to FDA (the "FOIA request") seeking certain documents related to the Engerix-B vaccine.

4. Paragraph 4 consists of Plaintiff's characterizations of this action and of records requested in the FOIA request, to which no response is required.

5. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. Admits, except to the extent Paragraph 6 contains legal conclusions to which no response is required.

7. Paragraph 7 consists of legal conclusions regarding jurisdiction and venue, to which no response is required.

8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations concerning a non-party.

9. Paragraph 9 consists of Plaintiff's characterizations of HHS's responsibilities and of legal conclusions, to which no response is required.

10. Paragraph 10 consists of Plaintiff's characterizations of a publication, to which no response is required. FDA respectfully refers the Court to the relevant publication for a complete and accurate statement of its contents.

11. Paragraph 11 consists of legal conclusions and characterizations of statutory provisions and case law, to which no response is required. FDA respectfully refers the Court to

the relevant statutory provisions and case law for a complete and accurate statement of their contents.

12. Paragraph 12 consists of legal conclusions and characterizations of statutory provisions, to which no response is required. FDA respectfully refers the Court to the relevant statutory provisions for a complete and accurate statement of their contents.

13. Paragraph 13 consists of legal conclusions and characterizations of statutory provisions, to which no response is required. FDA respectfully refers the Court to the relevant statutory provisions for a complete and accurate statement of their contents.

14. Paragraph 14 consists of legal conclusions and characterizations of statutory provisions and a congressional report, to which no response is required. FDA respectfully refers the Court to the relevant statutory provisions and congressional report for a complete and accurate statement of their contents.

15. Paragraph 15 consists of Plaintiff's characterizations of a CDC website and publication, to which no response is required. FDA respectfully refers the Court to the relevant website and publication for a complete and accurate statement of their contents.

16. FDA admits that it approved Engerix-B vaccine in 1989. Otherwise, Paragraph 16 consists of legal conclusions, to which no response is required.

17. Paragraph 17 consists of Plaintiff's characterizations of reports made to the Vaccine Adverse Events Reporting System, to which no response is required. To the extent a response is deemed required, Defendant admits that FDA co-sponsors the Vaccine Adverse Events Reporting System with the CDC, and otherwise respectfully refers the Court to the relevant reports for a complete and accurate statement of their contents.

18. Paragraph 18 consists of Plaintiff's characterizations of ICAN's FOIA request, to which no response is required. FDA admits that ICAN submitted the FOIA request dated June 21, 2019, and otherwise respectfully refers the Court to the relevant request for a complete and accurate statement of its contents.

19. Paragraph 19 consists of Plaintiff's characterizations of an e-mail from FDA dated July 9, 2019, to which no response is required. FDA admits that it sent an e-mail dated July 9, 2019, and otherwise respectfully refers the Court to the relevant e-mail for a complete and accurate statement of its contents.

20. Paragraph 20 consists of Plaintiff's characterizations of ICAN's counsel's response e-mail dated July 12, 2019, to which no response is required. FDA admits that it received a response from ICAN by e-mail dated July 12, 2019, and otherwise respectfully refers the Court to the relevant e-mail response for a complete and accurate statement of its contents.

21. Paragraph 21 consists of Plaintiff's characterizations of an FDA response dated July 26, 2019, to which no response is required. FDA admits that it responded to ICAN by e-mail dated July 26, 2019, and otherwise respectfully refers the Court to the relevant e-mail response for a complete and accurate statement of its contents.

22. Paragraph 22 consists of Plaintiff's characterizations of ICAN's counsel's response e-mail dated July 30, 2019, to which no response is required. FDA admits that it received a response from ICAN by e-mail dated July 30, 2019, and otherwise respectfully refers the Court to the relevant e-mail response for a complete and accurate statement of its contents.

23. Paragraph 23 consists of Plaintiff's characterizations of FDA's letter dated August 13, 2019, to which no response is required. FDA admits that it responded to ICAN by letter

dated August 13, 2019, which was later re-sent on September 9, 2019, and otherwise respectfully refers the Court to the relevant letter for a complete and accurate statement of its contents.

24. Paragraph 24 consists of Plaintiff's characterizations of ICAN's appeal dated November 22, 2019, to which no response is required. FDA admits that ICAN appealed the final response, and otherwise respectfully refers the Court to the relevant appeal for a complete and accurate statement of its contents.

25. Paragraph 25 and its accompanying footnote consist of Plaintiff's characterizations of this action, legal conclusions, and characterizations of statutory provisions, to which no response is required. FDA respectfully refers the Court to the relevant statutory provisions for a complete and accurate statement of their contents.

26. The portion of the amended complaint titled "Requested Relief" following Paragraph 25 contains Plaintiff's prayer for relief, to which no response is required. To the extent a response is deemed required, FDA denies that Plaintiff is entitled to the relief it seeks or to any relief.

DEFENSES

For further defenses, Defendant alleges as follows:

FIRST DEFENSE

Plaintiff's amended complaint should be dismissed in whole or in part to the extent it fails to state a claim on which relief may be granted.

SECOND DEFENSE

Some or all of the requested records or information may be exempt from disclosure, in whole or in part, under 5 U.S.C. § 552(b).

THIRD DEFENSE

The Court lacks subject matter jurisdiction over Plaintiff's requests for relief that exceed the relief authorized under FOIA, 5 U.S.C. § 552.

FOURTH DEFENSE

Plaintiff is not entitled to declaratory relief. *See* 5 U.S.C. § 552(a)(4)(B).

FIFTH DEFENSE

Plaintiff is not entitled to attorney fees under 5 U.S.C. § 552(a)(4)(E).

SIXTH DEFENSE

The case should be dismissed to the extent venue is improper in this Court under 5 U.S.C. § 552(a)(4)(B).

SEVENTH DEFENSE

Plaintiff's FOIA request is improper to the extent it does not reasonably describe the records requested. 5 U.S.C. § 552(a)(3)(A).

Defendant may have additional defenses which are not known at this time but which may become known through further proceedings. Accordingly, Defendant reserves the right to assert each and every affirmative or other defense that may be available, including any defenses available pursuant to Rules 8 and 12 of the Federal Rules of Civil Procedure.

WHEREFORE Defendant respectfully requests that the Court: (1) dismiss the amended complaint with prejudice; (2) enter judgment in favor of Defendant; and (3) grant such further relief as the Court deems just and proper.

Dated: March 24, 2020
New York, New York

Respectfully submitted,

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: /s/ Samuel Dolinger
SAMUEL DOLINGER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2677
E-mail: samuel.dolinger@usdoj.gov