UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	**AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff, as for its Amended Complaint against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. The National Childhood Vaccine Injury Act of 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34, granted economic immunity to pharmaceutical companies for the injuries caused by their vaccines. The responsibility for vaccine safety was therefore placed in the hands of the United States Department of Health and Human Services ("**HHS**") pursuant to 42 U.S.C. § 300aa-27(a) which provided, *inter alia*, that it "shall … make or assure improvements in … the licensing … of vaccines … in order to reduce the risks of adverse reactions to vaccines." The United States Food and Drug Administration ("**Defendant**" or "**FDA**") and the Centers for Disease Control and Prevention ("**CDC**") are agencies within HHS.

2. Before a drug or biologic is advertised to the public for use in a specific patient population, such as infants and children, it must be licensed by the FDA for use in that specific patient population. The FDA only provides such licensure upon a finding that the use of the drug or biologic in the specific patient population is safe and effective.

3. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a non-profit organization that advocates for informed consent with regard to all medical interventions. The CDC vigorously promotes the Engerix-B (hepatitis B) vaccine, recommending that babies receive an injection of this product at birth and then at one month and six months of life. ICAN, therefore, submitted a FOIA request to the FDA in June 2019 for copies of the clinical trials relied upon to license the Engerix-B vaccine for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine (the "**FOIA Request**"). ICAN wanted to review and share with the public the clinical trial reports and safety data relied upon when the FDA licensed this vaccine.

4. ICAN brings this action to challenge the FDA's failure to provide copies of any clinical trials it relied upon before licensing the Engerix-B vaccine as requested in the FOIA Request. Copies of these clinical trials should be readily accessible to the FDA, and it should welcome sharing these reports with the public to assure the public of the safety of administering the Engerix-B vaccine to, *inter alia*, babies on their first day of life, and at one month and six months of life.

PARTIES

5. Plaintiff Informed Consent Action Network is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

6. Defendant the United States Food and Drug Administration is an agency within the Executive Branch of the United States Government, organized within HHS. The FDA is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

7. This 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 within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

FACTS

8. The CDC recommends that newborn infants receive routine Engerix-B vaccinations. The CDC is the largest single purchaser, distributor, and advertiser of the Engerix-B vaccine in the United States.

I. HHS and its Agencies (FDA, CDC, etc.) are Responsible for Vaccine Safety

9. HHS, along with its agencies – including the FDA and CDC – are singularly responsible for vaccine safety. Part of this responsibility includes working to improve vaccine safety by creating and maintaining rigorous licensing requirements.

10. The genesis of how HHS became responsible for vaccine safety began in 1986 when Congress learned that the "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines." (Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994).) The remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market.

11. In response, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the "**1986 Act**"), in 1986. That Act virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 ("No person may bring a civil action for damages in the amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal

court for damages arising from a vaccine-related injury or death."); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) ("we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").

12. By granting manufacturers immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of nearly all other consumer products. Recognizing that it eliminated the incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress placed the responsibility for vaccine safety in the hands of HHS and its agencies, including the FDA. 42 U.S.C. §§ 300aa-1 to 300aa-34.

13. HHS' mandate to assure the safety of vaccines is codified at 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," and provides, in relevant part:

> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, *the Secretary shall* … make or *assure improvements in*, and otherwise use the authorities of the Secretary with respect to, the *licensing* … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(emphasis supplied.)

14. HHS, while responsible for vaccine safety, is simultaneously responsible for promoting vaccines and for defending against claims of vaccine injuries. For example, if an individual is injured by the Engerix-B vaccine or by any other vaccine, pursuant to the 1986 Act, the injured individual must bring a claim in the Vaccine Injury Compensation Program ("**VICP**"), administered in the Federal Court of Claims. In these actions, the Secretary of HHS is the respondent with the Department of Justice as its litigation counsel, and they regularly and

vigorously defend against any claim that a vaccine caused the alleged injury. 42 U.S.C. § 300aa-12; https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

15. At the same time, the CDC advertises, markets, and promotes Engerix-B vaccine to parents, medical providers, and the public at large. It recommends that every newborn infant should receive the first dose of this three-dose Hepatitis B vaccine within 24 hours of birth. (https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm). It publicizes this through fact sheets, podcasts, videos, and infographics.

II. Licensure of Drug or Biological by the FDA

16. Before a drug or biologic can be marketed for use in a specific patient population, such as children, it must be licensed by the FDA for use in that patient population. Such licensure is only provided if the FDA finds that the product is safe and effective for use in that patient population. The FDA licensed Engerix-B vaccine in 1989.[1]

17. There have been thousands of post-licensure reports of serious adverse events from the Engerix-B vaccine, including by its manufacturer and doctors administering this product, to the Vaccine Adverse Events Reporting System, which is co-managed by the FDA and CDC. Many of these were for serious injuries that would only be apparent months or years after injecting a baby with this product.

18. Therefore, on June 21, 2019, ICAN submitted a FOIA Request to the FDA, which requested:

> **A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine.**

[1] Engerix-B's ingredients include, *inter alia*, aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate.

19. On July 9, 2019, the FDA sent an email which stated in relevant part:

> The subject requests do not reasonably describe the records that you are seeking in a way that the records can be identified and located. Per our regulation in Title 21 CFR 20.40(b) "A request should include all pertinent details that will help identify the records sought." Although you have identified the brand name of the vaccine of interest, as well as a date range, you have not provided information related to the clinical trial(s) for which you are seeking reports in a way that allows us to search our record systems without reading all the records in the application file and trying to identify which clinical studies may have had "a safety review period longer than 7 days."

20. On July 12, 2019, counsel for ICAN responded as follows:

> We are seeking the:
>
> 1. **pre-licensure clinical trials**;
> 2. relied upon by the FDA;
> 3. to approve the listed vaccines;
> 4. for babies and children; and
> 5. that had a safety review period longer than seven days.
>
> These two requests are very specific reasonably describe the records sought. Kindly confirm that you are withdrawing your objection.

21. On July 26, 2019, the FDA provided the following response letter:

> **2019-5539 (IR 0133)**
>
> The original request was worded: *A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-8 for babies and children in 1986 that had a safety review period longer than seven days following administration of this vaccine.*
>
> In the email below, you amend the wording to:
> 1. ***pre-licensure clinical trials****;*
> 2. *relied upon by the FDA;*
> 3. *to approve the listed vaccines;*
> 4. *for babies and children; and*
> 5. *that had a safety review period longer than seven days.*
>
> Thank you for the clarification that you are seeking pre-licensure clinical trial information for Engerix B. As I discussed with you on the phone, we would interpret this to mean the clinical trial reports

> submitted by the sponsor for the original BLA for Engerix B (STN 103239/0). I also explained that we are unable to search or locate records by information that may be included in the records, i.e. *"that had a safety review period longer than seven days."*
>
> ***
>
> Do you agree to amend the wording of this request to *"The clinical trial reports submitted by the sponsor for the original 8LA for Engerix B (STN 103239/0)"?*

22. On behalf of ICAN, counsel responded on July 30, 2019, in part, as follows:

> After discussing the below with my client, they do not agree to modify the language of the request[] numbered [] 2019-5539 (IR 0133).

23. On August 13, 2019, the FDA provided a Final Response Letter which was subsequently resent on September 9, 2019, and stated, in part, as follows:

> In an email on July 9, 2019, we explained that your request did not reasonably describe the records that you are seeking, and we asked you to provide more information that better describes the records that you are requesting. In an email on July 12 you provided slightly amended wording of your request. In a phone conversation on July 25 we discussed the wording you provided in your July 12 email. Then by email on July 26 we wrote to you to confirm our understanding of the records that you are seeking. During the phone conversation we discussed that we would interpret the amended wording of your request to mean the clinical trial reports submitted by the sponsor for the original BLA for Engerix B (STN 103239/0) an also explained that we are unable to search or locate records by information that may be included in the records, i.e. “that had a safety review period longer than seven days." We asked if you agreed with the interpretation of your amended request; that it is requesting, "The clinical trial reports submitted by the sponsor for the original BLA for Engerix B (STN 103239/0)". In an email on July 30 you informed us that your client does not agree.
>
> As we are unable to search or locate records in the way in which you describe the records, we are closing your FOIA request. Please feel free to resubmit a FOIA request in the future providing more details and describing the records you are seeking.

24. On November 22, 2019, ICAN appealed the FDA's failure to provide responsive records to the FOIA Request, but still received no responsive documents from the FDA.

25. As a result, ICAN brings this action to appeal the FDA's non-response to the FOIA Request.[2]

Requested Relief

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order declaring that it was unlawful for the FDA to fail to disclose documents responsive to the FOIA Request;

c. Enter an Order directing the FDA to, within 30 days of issuance of the order, disclose a copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine;

d. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

[2] It is also noted that the FDA has a statutory duty separate and apart from the Freedom of Information Act to disclose the clinical trial data it relied upon to license Engerix B. Section 355(l) of Title 21, entitled "Public disclosure of safety and effectiveness data and action package," provides that: "Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown." 21 USC § 355(l).

e. Grant such other and further relief as the Court may deem just and proper.

Dated: March 16, 2020

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