UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Plaintiff, as for its 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 varicella (chickenpox) vaccine. ICAN, therefore, submitted a FOIA request to the FDA in September 2018 for copies of the clinical trials relied upon to license the varicella vaccine in 1995 (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. The FDA failed to produce the clinical trial reports sought by the FOIA Request. ICAN brings this action to challenge the FDA's failure to provide copies of the clinical trials it relied upon prior to licensing the varicella vaccine. Copies of these clinical trials should be readily accessible to the FDA and it should welcome sharing these reports with the public in order to assure the public of the safety of administering the varicella vaccine.

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. Since March 17, 1995, CDC has recommended that children 12 months and older receive routine varicella vaccinations. CDC is the largest single purchaser, distributor and advertiser of the varicella vaccine in the United States.

I. The 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 through creating and maintaining rigorous licensing requirements.

10. The genesis of how the 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:

> (a) 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 varicella 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.

II. CDC Advertises, Markets & Promotes the Varicella Vaccine to Children and Adults

15. The CDC advertises, markets, and promotes varicella vaccine to parents, medical providers, and the public at large. It recommends that every person over 12 months should receive the varicella vaccine. It publicizes this through fact sheets, podcasts, videos, and infographics. *See, e.g.*, https://www.cdc.gov/chickenpox/multimedia.html (CDC videos/podcasts include those entitled "Nobody Wants Chicken Pox!," "One family's struggle with chickenpox," and "Chickenpox--#Vaccines by the Numbers.")

III. 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 varicella vaccine in 1995.

17. Nevertheless, post-licensure reports of serious adverse events from the varicella vaccine conducted by the Institute of Medicine and other randomized trials found that 26% of children had unexpected adverse events from this vaccine.

18. Given the CDC's widespread marketing of the varicella vaccine, ICAN was concerned about this higher than expected rate of adverse events. Therefore, ICAN sought copies of the clinical trial reports that the FDA relied upon when licensing the varicella vaccine.

19. On September 10, 2018, ICAN submitted a FOIA Request to the FDA, which requested:

> **A copy of the clinical study report for each clinical trial relied upon by the FDA when approving Varicella in 1995.**

20. On September 12, 2018, the FDA sent an acknowledgment letter which stated in relevant part: "The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding: VARICELLA—CLNCL TRIAL STUDY APRVL 1995 We will respond as soon as possible and may charge you a fee for processing your request."

21. Following this response letter, the FDA produced no documents responsive to the FOIA Request. The FDA failed to respond within the 20 days required by the FOIA statute, and it did not seek an extension of the statutory processing time.

22. On April 17, 2019, ICAN appealed the FDA's failure to provide responsive records to the FOIA Request, but still received no responsive documents from the FDA.

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

IV. Basic Information Regarding Varicella Vaccine

24. A summary of a portion of the production process for the varicella vaccine is provided in Plotkin's Vaccines, 7th Edition, considered the authoritative medical textbook on vaccinology:

> Seed lots of Oka vaccine were prepared from virus passed 11 times in human embryo lung fibroblast cells, 12 times in guinea pig fibroblast cells, and five times in HDC [Human Diploid Cells]. Manufacturers add from three to nine additional passages in HDC to prepare enough vaccine to meet marketing needs.

25. The following is the list of ingredients published by the CDC for each varicella containing vaccine:

Brand Name	Manufacturer	CDC's List of Ingredients
Varivax *Frozen*	Merck	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varivax *Refrigerator Stable*	Merck	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
ProQuad	Merck	chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate potassium chloride, neomycin, bovine serum albumin

V. The FDA Has a Duty to Disclose Application Submitted to Approve Varivax

26. 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 Varivax.

27. 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).

28. No extraordinary circumstances exist which should allow the FDA to withhold disclosure of the application submitted to approve Varivax.

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 the clinical trials it relied upon when licensing the varicella vaccine;

c. Enter an Order directing the FDA to, within 30 days of issuance of the order, disclose the clinical trials it relied upon when licensing the varicella 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

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

Dated: November 4, 2019

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