**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."

2. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a non-profit organization that advocates for informed consent with regard to all medical interventions. ICAN and its founder, Del Bigtree, have received a litany of complaints from members of the public that they had a miscarriage shortly after receiving an influenza vaccine (the "**flu shot**") or a Tdap vaccine. A recent study funded by the CDC also indicated an over seven-fold increased risk of miscarriage after certain flu shots.

3. The Centers for Disease Control and Prevention (the "**CDC**") vigorously promotes the flu shot to pregnant women, advising that every pregnant woman should receive a flu shot during pregnancy. The CDC also vigorously promotes the flu shot to medical providers, directing

them that the standard of medical care is to administer a flu shot to every pregnant woman at any point during pregnancy.

4. Before a drug or biologic is advertised to the public for use in a specific patient population, such as pregnant women, it must be licensed by the United States Food and Drug Administration ("**Defendant**" or "**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.

5. ICAN, therefore, submitted a FOIA request to the FDA for copies of the clinical trials relied upon to license the flu shot for pregnant women (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 the flu shot for use in pregnant women.

6. The FDA failed to produce the clinical trial reports requested in the FOIA Request. ICAN brings this action to challenge FDA's failure to provide copies of the clinical trials it relied upon prior to licensing the flu shot for pregnant women. 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 flu shot to pregnant women.

## PARTIES

7. 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.

8. 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

9. 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

10. Since 2004, the CDC has recommended that pregnant women regardless of gestational age receive routine influenza vaccinations. The CDC is the largest single purchaser, distributor and advertiser of flu shots in the United States.

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

11. 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.

12. The genesis of how HHS became singularly responsible for vaccine safety was that by 1986 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.

13. 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, which 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").

14. 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 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.

15. 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—
>
> (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
>
> (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the *licensing*, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(emphasis supplied.)

16. HHS, while responsible for vaccine safety, is simultaneously responsible for promoting vaccines and for defending against claims of vaccine injuries. If an individual is injured by a flu shot, 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 the flu shot caused injury. 42 U.S.C. § 300aa-12; https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

## II. CDC Vigorously Advertises, Markets & Promotes the Flu Shot to Pregnant Women

17. The CDC vigorously advertises, markets and promotes to pregnant women, medical providers, and the public-at-large that every pregnant woman should receive a flu shot. The following are examples of how the CDC markets and promotes the flu shot for pregnant women.

18. The CDC website includes the following graphic under the header "Pregnant Women & Influenza (Flu)" on its main page regarding the flu shot and pregnancy:


The CDC website then specifically asserts that: "Pregnant women should get a flu shot."

19. In the following CDC advertisements, the CDC claims that as "part of your prenatal care, your doctor recommends getting a flu shot anytime during your pregnancy":

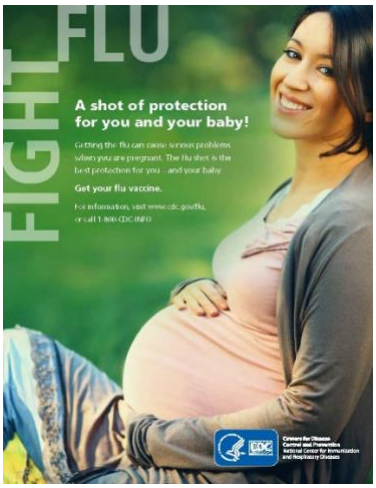


Copies of these advertisements are available at https://www.cdc.gov/flu/pdf/freeresources/pregnant/obgyn-caucasian-card.pdf; https://www.cdc.gov/flu/pdf/freeresources/pregnant/obgyaa-flu-card.pdf; https://www.cdc.gov/flu/pdf/freeresources/spanish/obgyn-flu-sp.pdf

20. The following CDC circular is titled "Pregnant? You Need a Flu Shot!":


A copy of the CDC circular is available at https://www.cdc.gov/flu/pdf/freeresources/pregnant/flushot_pregnant_factsheet.pdf

21. The following CDC flyer tells pregnant women to "Get your flu vaccine.":

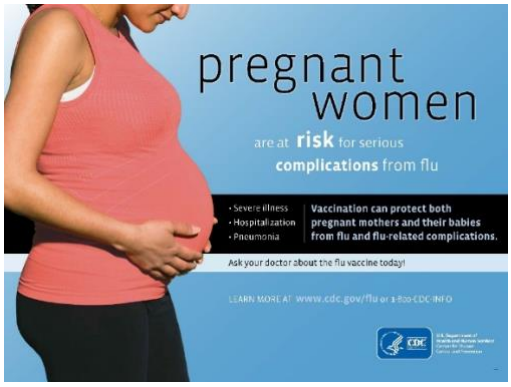



A copy of the flyer is available at https://www.cdc.gov/flu/pdf/freeresources/pregnant/flu-shot-protect-pregnancy.pdf

22. The following CDC advertisement tells pregnant women to receive the flu shot:


A copy of this advertisement is available at https://www.cdc.gov/flu/pdf/partners/flu-pregnancy-infographic-updated.pdf

23. The following is the English and Chinese version of a CDC poster:





Copies of these posters are available at https://www.cdc.gov/flu/pdf/freeresources/pregnant/flu-risk-pregnancy-poster.pdf; https://www.cdc.gov/flu/pdf/freeresources/pregnant/pregnant-women-influenza-chinese.pdf

24. The CDC also has videos, including on YouTube, and podcasts telling pregnant women to receive the flu shot, including videos/podcasts entitled "Pregnant Women: Answers to Common Questions about the Flu Vaccine," "Preventing Flu During Pregnancy, A Cup of Health with CDC," and "Preventing Flu During Pregnancy, A Minute of Health with CDC."

25. The CDC further issues an annual letter to health care providers telling them to give the flu shot to pregnant women. Its most recent letter states: "Studies have shown that pregnant women who received a vaccine recommendation from a health care provider were more likely to be vaccinated than those who did not receive a recommendation. … All pregnant women, or those who might be pregnant during the upcoming flu season, should get a flu vaccine." A copy of the letter is available at https://www.cdc.gov/flu/pdf/professionals/pregnant-women-letter_september-2017-2018.pdf

## III. Licensure of Drug or Biological by the FDA

26. Before a drug or biologic can be marketed for use in a specific patient population, such as pregnant women, it must be licensed by the FDA for use in that patient population. Such licensure is only provided if the FDA finds it is safe and effective for use in that patient population.

27. Given the CDC's widespread marketing of the flu shot for use by pregnant women, ICAN sought copies of the clinical trial reports the FDA relied upon when licensing the flu shot for use in pregnant women.

28. ICAN's request was prompted by numerous complaints it and its founder, Del Bigtree, have received from pregnant women asserting they had a miscarriage shortly after receiving a flu shot or Tdap vaccine. ICAN also recently became aware of a 2017 study funded by the CDC and authored by doctors working for the CDC, which found a 770% increase in the rate of miscarriage when certain flu shots were administered in successive flu seasons. This study is available at https://www.ncbi.nlm.nih.gov/pubmed/28917295. Another study, which was double-blind and placebo-controlled, found no difference in the rate of influenza between receipt of the flu shot or placebo, but did find a 440% increased rate of non-influenza respiratory infections among the group receiving the flu shot. This study is available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/

29. Given these troubling reports, ICAN submitted a FOIA Request to the FDA on September 21, 2018, which requested:

> **A copy of the report for each clinical trial relied upon by the FDA when approving for use by pregnant women any influenza vaccine currently approved by the FDA.**

30. On October 10, 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:
>
> CLNCL TRIAL FOR APRVL OF INFLUENZA VACCINE FOR PREGNANT WOMEN
>
> We will respond as soon as possible and may charge you a fee for processing your request.

31. Following this response letter, the FDA produced no documents responsive to the FOIA Request. The FDA failed to respond within 20 days, nor did it seek an extension of the statutory processing time.

32. Thirty-three days after filing the FOIA Request, on October 24, 2018, ICAN appealed the FDA's failure to provide responsive records to the FOIA Request. Thereafter, the FDA advised on a phone call that it may not have records responsive to the FOIA Request.

33. On November 9, 2018, the FDA provided a letter asserting that, in relevant part, "We have no records responsive to your requests."

34. It is a violation of Federal law, including HHS regulations, to advertise and market a vaccine to a particular population, like pregnant women, without it first being licensed for that population. Given that the CDC is marketing, advertising and promoting the flu shot for pregnant women, and has repeatedly advised pregnant women to receive the flu shot, it follows that the FDA must have licensed the flu shot for pregnant women. If the FDA licensed the flu shot for

pregnant women, it must have done so based on clinical trials. Therefore, the FDA must have copies of the clinical trials it relied on, and the FDA must have been incorrect when it stated that it has no such clinical trials to produce in response to the FOIA Request.

35. Moreover, because the Secretary of HHS, which oversees the FDA, is required to "make or assure improvements in … the licensing … of vaccines … in order to reduce the risks of adverse reactions to vaccines," it appears improbable that HHS, or any of its agencies such as the CDC, would vigorously advertise, market and promote a vaccine for an unlicensed use.

36. Promoting an unlicensed use of a vaccine to the public would plainly violate and be antithetical to HHS's statutory duty. The FDA's response to the FOIA Request that it has no responsive records is, therefore, unlikely to be correct. The FDA clearly must not have engaged in an appropriate search to identify the clinical trials it relied upon when licensing the flu shot for use in pregnant women.

37. As a result, ICAN brings this action to appeal the FDA's November 9, 2018 final determination that it has no records responsive to the FOIA Request. The FDA has plainly failed to undertake a thorough review of its records to locate and produce the clinical trials it relied upon before licensing the flu shot for use in pregnant women.

## IV. Basic Information Regarding Flu Shots Administered to Pregnant Women

38. A summary of the production process for flu shots is provided in Plotkin's Vaccines, 7th Edition, considered the authoritative medical textbook on vaccinology:

> All influenza viruses are replicated individually in substrates of animal origin and are harvested in liquid form. The majority of influenza vaccine viruses are replicated in the allantoic cavities of embryonated hen's eggs … [or are] produced using mammalian cell lines (MDCK [Madin-Darby canine kidney] or Vero). [A] variety of detergents, including deoxycholate, tri-*N*-butyl phosphate, Triton X-100, Triton N101, and cetyltrimethylammonium bromide, are … used for commercial vaccine preparation. … Aminoglycoside antibiotics are used in some production schemes to reduce bacterial

> growth in eggs during processing steps. … Thimerosal, an organic mercury-containing compound … is present in inactivated influenza virus vaccines produced for multidose presentation. … Alternative preservatives such as 2-phenoxyethanol and phenol have been used in other vaccines... Either formalin or β-Propiolactone is used in influenza vaccine to inactivate the viruses.

39. The following is the list of flu shots the CDC advertises for use in pregnant women during the 2018-2019 flu season:

| Brand Name | Manufacturer | Publicly Disclosed Ingredients |
|---|---|---|
| Flucelvax (ccIIV4) | Seqirus | Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone |
| Afluria(IIV4) Afluria(IIV3) | Seqirus | sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multidose vials) |
| Fluarix(IIV4) | GlaxoSmith-Kline | octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride |
| FluLaval (IIV4) | ID Biomedical Corp. of Quebec | ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials) |
| Fluzone (IIV4) | Sanofi Pasteur | formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphatebuffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose |
| Flublok Quadrivalent (RIV4) | Sanofi Pasteur | sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts |

Available at https://www.cdc.gov/flu/protect/vaccine/vaccines.htm and https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf

**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 flu shot for use in pregnant women;

c. Enter an Order directing HHS to, within 30 days of issuance of the order, disclose the clinical trials it relied upon when licensing the flu shot for use in pregnant women;

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: December 3, 2018

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