UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 the Secretary of HHS "shall … make or assure improvements in … the licensing, manufacturing, … adverse reaction reporting, … and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."

2. To track HHS's fulfillment of these vaccine safety obligations, 42 U.S.C. Section 300aa-27(c) provided that, "Within 2 years after December 22, 1987, and periodically thereafter, the Secretary [of HHS] shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period."

3. On May 31, 2017, Robert F. Kennedy, Jr. and Plaintiff's founder, Del Bigtree, along with a handful of other individuals, had a two-hour meeting regarding vaccine safety with the Counselor to the Secretary of HHS, the Director of the National Institutes of Health ("**NIH**"), Principal Deputy Director of the NIH, and the Directors from various institutes at the NIH. During that meeting, Plaintiff and Robert F. Kennedy, Jr. became concerned that HHS was not faithfully fulfilling its obligations under 42 U.S.C. § 300aa-27(a). Plaintiff therefore decided to submit a request, pursuant to the Freedom of Information Act (5 U.S.C. § 552) ("**FOIA**"), to obtain copies of the reports the Secretary of HHS submitted to Congress pursuant to 42 U.S.C. § 300aa-27(c) which should detail the actions taken by HHS pursuant to 42 U.S.C. § 300aa-27(a) to improve vaccine safety.

4. On August 25, 2017, Plaintiff submitted a FOIA request to the HHS for: "Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c)." (the "**FOIA Request**"). HHS failed to timely respond to the FOIA Request. Plaintiff brings this action to challenge HHS's failure to respond and provide copies of its reports to Congress pursuant to this section, copies of which HHS should have readily accessible.

PARTIES

5. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") 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 Department of Health and Human Services ("**Defendant**" or "**HHS**") is a department within the Executive Branch of the United States Government and 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

I. Background

8. 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.

9. In response, Congress passed the National Childhood Vaccine Injury Act, in 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the "**1986 Act**"), 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 pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").

10. By granting immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces that are generally relied upon to assure the safety of all other products. Recognizing that the 1986 Act eliminated the incentive for vaccine makers to assure the safety of their vaccine products, the 1986 Act explicitly places the responsibility for vaccine safety in the hands of the United States Department of Health and Human Services ("**HHS**"). 42 U.S.C. §§ 300aa-1 through 300aa-34.

11. To that end, Section 300aa-1, entitled "Establishment," provides that "The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."

12. Section 300aa-2, entitled "Program responsibilities," provides that the National Vaccine Program's responsibilities shall include, *inter alia*:

> (1) Vaccine research. The Director of the Program shall … coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to … prevent adverse reactions to vaccines.
>
> (2) Vaccine development. The Director of the Program shall … coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for

> International Development to develop the techniques needed to produce safe and effective vaccines.
>
> (3) Safety and efficacy testing of vaccines. The Director of the Program shall … coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.
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> * * *
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> (7) Evaluating the … adverse effects of vaccines and immunization activities. The Director of the Program shall … coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring … adverse effects of vaccines and immunization activities.

13. Reflecting the importance of HHS's responsibility to assure vaccine safety, Section 300aa-27(a), entitled "Mandate for safer childhood vaccines," puts the following responsibility directly in the hands of the Secretary of HHS:

> (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.

14. To assist the Secretary of HHS in performing these duties, Section 300aa-27(b) directs the Secretary to establish a task force responsible for making recommendations to the Secretary concerning implementation of the requirements of Section 300aa-27(a). This task force is entitled the "task force on safer childhood vaccines." (the "**Task Force**" or "**Task Force on Safer Childhood Vaccines**"). 42 U.S.C. § 300aa-27(b). The Director of the NIH is the chair of the Task Force, which by statute also includes the Commissioner of the FDA and the Director of the CDC. *Id.*

15. As provided in Section 300aa-27(b)(3):

> In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

16. The Task Force, chaired by the Director of NIH, is therefore statutorily responsible, pursuant to Section 300aa-27(b), to provide the Secretary of HHS with recommendations concerning implementation of the requirements of Section 300aa-27(a).

17. To assure the Secretary of HHS takes action based on the recommendations made by the Task Force and is otherwise fulfilling its important obligations pursuant to Section 300aa-27(a) to assure the safety of the vaccines administered to children in the United States, Section 300aa-27(c) provides that:

> Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

18. The rapid growth in the number of pediatric vaccines since passage of the 1986 Act has only increased the need for HHS to faithfully fulfill its obligations under 42 U.S.C. § 300aa-1

et seq. to assure the safety of vaccines used in this country. In 1983, the CDC's childhood vaccine schedule included 11 injections of 4 vaccines. (CDC, 1983 Childhood Immunization Schedule *available at* https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg.) As of 2018, the CDC's childhood vaccine schedule had grown to include 56 injections of 30 different vaccines. (CDC, 2018 Childhood Immunization Schedule *available at* https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)

19. Robert F. Kennedy, Jr. and Plaintiff's founder, Del Bigtree, along with a few other individuals concerned about vaccine safety, had a two-hour meeting at the NIH in Bethesda, Maryland on May 31, 2017 with the Counselor to the Secretary of HHS, Director of the NIH, the Principal Deputy Director of the NIH, and the Directors from various institutes at the NIH. During that meeting regarding vaccine safety, Plaintiff and Robert F. Kennedy, Jr., became concerned that HHS was not fulfilling its obligations under 42 U.S.C. § 300aa-27(a). Plaintiff therefore decided to submit a FOIA request to obtain copies of the reports the Secretary of HHS was required to submit to Congress pursuant to 42 U.S.C. § 300aa-27(c), copies of which HHS should have readily available.

II. The FOIA Request

20. On August 25, 2017, Plaintiff sent the FOIA Request via email and FedEx to HHS.

21. On November 8, 2017, HHS finally provided an acknowledgement letter for the FOIA Request, which stated in relevant part:

> This acknowledges receipt of your August 25, 2017, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning: "**Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate**

> **by the Secretary of HHS pursuant to 42 U.S.C. $300aa-27(c) [sic].**".
>
> We received your request on **August 28, 2017**.
>
> We have initiated a search to locate records falling within the scope of your request. If our searching units advise us that you have requested a voluminous amount of records that require extensive search and examination, my staff will contact you shortly to discuss your willingness to modify your request.
>
> The FOIA requires that we respond to your request within 20 working days of its receipt in this office. Please note the following unusual and exceptional circumstances that will impact our response time: (1) we will need to search for and collect records from components and/or field offices external to this office; and (2) because we receive a very heavy volume of FOIA requests, we will process your request in line with our established policy of "first in, first out" case processing. If either of these circumstances prevents our office from responding within the 20 working day timeframe, we will utilize a 10 working day extension to process your request, as permitted pursuant to the FOIA.

(Emphasis in original.)

22. HHS never requested that Plaintiff modify the FOIA Request. HHS also failed to respond within 20 days nor did it seek a 10 day extension thereafter for responding to the FOIA Request. HHS also did not respond to the numerous follow-up inquiries for a status update regarding the FOIA Request, including inquiries sent on January 23, 2018, January 30, 2018, and February 6, 2018.

23. On March 13, 2018, Plaintiff appealed the FOIA Request to Deputy Agency Chief FOIA Officer at HHS and received an acknowledgment of this appeal from HHS which provided, in relevant part: "This is in response to your Freedom of Information Act (FOIA) appeal, dated: **March 13, 2018**, concerning the constructive denial of your initial request, which is assigned case number 2017-01119-FOIA-OS. We received your appeal on **March 13, 2018**." (emphasis in

original). HHS, however, failed to respond within 20 days nor did it seek an extension of the statutory processing time for this administrative appeal.

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 Defendants' to fail to timely either (1) disclose the reports transmitted by HHS to Congress pursuant to 42 U.S.C. § 300aa-27(c), (2) assert an exemption for such reports, or (3) state that no such reports exist;

c. Enter an Order directing HHS to, within 20 days of issuance of the order, either (1) make available to Plaintiff any and all reports responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such reports; or (3) state that no such reports exist;

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: April 12, 2018

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