UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION Defendant.	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

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

INTRODUCTION

1. In 1986, Congress passed the National Childhood Vaccine Injury Act, 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 preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects").

2. By granting pharmaceutical companies immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of these often mandatory consumer products.

3. Recognizing that it eliminated the financial incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress placed the responsibility for vaccine safety in the hands of the Department of Health and Human Services ("**HHS**") and its agencies pursuant

to 42 U.S.C. § 300aa-27(a) ("Mandate for safer childhood vaccines"), which provides, *inter alia*, that the Secretary of HHS "shall … make or assure improvements in, and otherwise use the authorities of the Secretary with respect to … research on vaccines, in order to reduce the risks of adverse reactions to vaccines."

4. In carrying out this responsibility, the Centers for Disease Control and Prevention's ("**CDC**") Immunization Safety Office ("**Safety Office**") plays a central role in ensuring the safety of administering the approximately 74 doses of vaccine on the CDC's Child and Adolescent Immunization Schedule. Most of these vaccines, which are vigorously promoted by the CDC for injection into American babies, are manufactured and sold by the pharmaceutical companies GlaxoSmithKline ("**GSK**"), Sanofi S.A. ("**Sanofi**") and Merck & Co. ("**Merck**").

5. The Safety Office's core function is to act as a watchdog over the pharmaceutical companies that manufacture and sell these products in order to assure their safety as they are sold and injected into millions of American children. The Director of the Safety Office is Frank DeStefano.

6. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a non-profit organization that advocates for informed consent regarding all medical interventions.

7. In order to assess whether Frank DeStefano has been fulfilling his responsibilities as a watchdog over these companies, and pursuant to CDC's commitment to "openness and accountability," ICAN submitted a FOIA request (the "**FOIA Request**") to the CDC requesting the following:

> 1) Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees of GlaxoSmithKline while the Acting Director or the Director of the Immunization Safety Office.
>
> 2) Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees

of Sanofi while the Acting Director or the Director of the Immunization Safety Office.

3) Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees of Merck & Co. while the Acting Director or the Director of the Immunization Safety Office.

8. The CDC located 281 pages of responsive records, withheld 81 of those pages in full and partially redacted an additional 30 pages (the "**Redacted Emails**"). The CDC alleged that redactions were made pursuant to Exemption 5 (privileged communications within or between agencies) and Exemption 6 (information that would invade personal privacy) provided for in 5 U.S.C. §552.

9. Upon receipt of the responsive documents, ICAN undertook to evaluate the propriety of the redactions but was unable to because the information necessary to do so was itself redacted. Therefore, ICAN requested that the CDC resend the redacted documents leaving basic information, such as "to," "from," etc. on each page so that it could assess the appropriateness of the redactions. ICAN further requested a log of the full-page redactions with an explanation of the basis for the redactions, including copies that did not redact the basic "to," "from", etc., content of each page.

10. The CDC failed to respond to ICAN's request. ICAN appealed and the CDC failed to respond to the appeal.

11. ICAN brings this action to challenge the CDC's failure to respond to its request and appeal, and to seek an order compelling the CDC to produce unredacted copies of the Redacted Emails.

PARTIES

12. 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.

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

JURISDICTION AND VENUE

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

15. HHS, along with its agencies, including the CDC, are singularly responsible for vaccine safety.

16. 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.

17. 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").

18. 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 CDC. 42 U.S.C. §§ 300aa-1 to 300aa-34.

19. HHS's 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.

20. In executing its vaccine safety duties, HHS must be extra vigilant to avoid conflicts of interest, including those with pharmaceutical companies. This is because in addition to its vaccine safety duties, HHS is simultaneously responsible for promoting vaccines and for defending

against claims of vaccine injuries. Indeed, the CDC is the single largest purchaser and distributor of vaccines in the country. Through its Vaccines for Children Program (**"VFC"**), created in 1993, the CDC promotes and distributes approximately forty percent of the vaccines given to children in America without charge. The CDC purchases almost all of these vaccines from Merck, Sanofi and GSK. In 2019 alone, the CDC entered into contracts to purchase and distribute up to $5.1 billion of those companies' vaccine products. See https://www.fbo.gov/spg/HHS/CDCP/PGOA/75D301-19-R-67848/listing.html

21. Not only does HHS promote, purchase and distribute vaccines, it also defends against legal claims that these vaccines cause any injury. If a vaccine injures an individual, the injured individual must (pursuant to the 1986 Act) 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 injury. 42 U.S.C. § 300aa-12; https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

II. The Safety Office's Critical Role Regarding Vaccine Safety

22. With no liability for injuries caused by their vaccine products, the importance placed on the CDC's responsibilities regarding vaccine safety are acute. Unlike other industries in which liability, or potential liability, make companies self-interested in assuring safety, this check does not exist for vaccine products, including those sold by Merck, Sanofi and GSK.

23. The central office responsible for vaccine safety within the CDC is the Safety Office. As the CDC explains, the Safety Office "plays a vital role in ensuring [the] nation's vaccine safety." It is supposed to be a critical watchdog over all vaccine manufacturers, including Merck, Sanofi and GSK, to assure the safety of their vaccine products.

24. Given the enormous amount of money that CDC spends with Merck, Sanofi and GSK, and the critical role that the Safety Office plays, ICAN wanted to review the communications that Frank DeStefano, the Director of the Safety Office, has had with those three pharmaceutical giants. ICAN therefore sought communications between Director DeStefano and Merck, Sanofi and GSK. If the Safety Office was performing its functions, the CDC should have welcomed disclosure of these emails so that ICAN could disseminate the robust oversight conducted by the Safety Office.

25. Disclosing these emails would also have furthered the CDC's stated commitment to openness and accountability. https://www.cdc.gov/od/foia/index.htm ("CDC ensures its science and research activities, and its employees comply with federal laws, regulations, and policies in order to exercise the highest level of scientific integrity. At the core of CDC's mission is information sharing—not just health information and disease study results, but information CDC gathers as part of a continuous process of putting information into action. As a science-based agency funded by U.S. taxpayers, CDC is committed to openness and accountability.")

III. The Freedom of Information Act Request

26. The FOIA requests submitted by ICAN provided as follows:

1. Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees of GlaxoSmithKline while the Acting Director or the Director of the Immunization Safety Office.

2. Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees of Sanofi while the Acting Director or the Director of the Immunization Safety Office.

3. Any communications sent or received by Frank DeStefano to or from representatives, directors, officers, or employees of Merck & Co. while the Acting Director or the Director of the Immunization Safety Office.

27. The CDC provided a final response letter (the "**Final Response Letter**") to the FOIA Request on September 12, 2018, which stated in relevant part:

> We located 281 pages of responsive records, of which 81 pages are withheld in full. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions 5 and 6.
>
> Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include drafts and business plan.
>
> Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as participant passcode, personal cell phone and email address, and we have determined that the individual to whom this information pertains have a substantial privacy interest in withholding it.

28. The CDC's claim that Exemption 5 applied to some of the responsive emails was inappropriate, since that exemption applies to inter-or-intra agency communications and the FOIA Request only sought communications between Director DeStefano and pharmaceutical companies. Therefore, on October 10, 2018, ICAN responded to the Final Response Letter and requested the following:

The pages that have been redacted in full do not provide sufficient unredacted content or information to make an assessment regarding whether the redaction was appropriate. Please resend the production leaving basic information, such as "to," "from," etc. on each page, so that such an assessment can be made on our end. Please also provide a log for the full-page redactions with an explanation of the basis for withholding and the basic content of each.

29. On October 31, 2018, the CDC responded as follows:

The information you seek can be located in your final response letter and your responsive documents.

"Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include draft correspondence and draft presentations."

As you read your responsive records, you will be able to see the specific type of information withheld. The emails prior to redacted pages will tell you what is redacted. For example, one email with the subject "CDC Ebola vaccine study-draft AEFI Prevention Form 11 10 14-3pm1dv+FT.docx" tells you the attachment that was redacted. Therefore, the information you seek can be found in your final response letter and your responsive documents.

30. On November 16, 2018, ICAN responded to the CDC and stated in relevant part:

Many of the pages that are blank just had a smudge at the top of the page. Please resend such that each page has, at the least, some exemption number at the top.

> Also, after review of the production, we have questions about the thoroughness of the review that resulted in this production. Please describe what steps were undertaken to produce this production.

31. The CDC did not respond to ICAN's November 16, 2018 request.

32. On December 18, 2018, ICAN submitted an appeal to the FOIA Request (the "**Appeal**"), and requested that the CDC produce the documents responsive to the FOIA Request within 20 days, "provide details on how the search was conducted" and provide "an itemized, indexed inventory of every agency record or portion thereof responsive to the FOIA Request which the CDC asserted to be exempt from disclosure, accompanied by a detailed justification statement covering each refusal to release records in accordance with the indexing requirements of *Vaughn v. Rosen*, 484 F. 2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974)." ("**Vaughn Index**").

33. The CDC provided an acknowledgment letter dated December 18, 2018, and assigned the Appeal tracking number FOIA Case 18-00802. Nevertheless, the CDC never substantively responded to the Appeal. ICAN therefore brings this action to challenge the CDC's redactions, its failure to explain how its search was conducted, and its failure to provide a *Vaughn* Index.

34. ICAN challenges the CDC's redactions pursuant to Exemption 5 for a number of reasons. First, the CDC failed to provide any specificity or detail as to why the Redacted Emails qualify for this exemption. *See*, *Judge Rotenberng Educ. Ctr., Inc. v. United States FDA*, 376 F. Supp. 3d 47, 65 (D.D.C. 2019) (holding that "[e]xemption 5 claims must be supported with specificity and [in] detail"). At best, the CDC's Final Response Letter dated September 12, 2018 stated that the Redacted Emails included "drafts and business plan," while the CDC's email of October 31, 2018 stated that the Redacted Emails contained "draft correspondence and draft presentation," contradicting its earlier assertion. Putting aside the contradiction, this is patently insufficient detail to support the CDC's extensive redactions.

35. Second, the CDC bears the burden of establishing the right to withhold the requested documents, and the conclusory assertions of privilege set forth by the CDC in the Final Response Letter are not sufficient to meet this burden. *Brennan Ctr. for Justice at NY Univ. Sch. of Law v Dept. of Homeland Sec*., 331 F. Supp. 3d 74, 83 (S.D.N.Y. 2018) (stating that "[t]he government bears the burden of demonstrating that an exemption applies to each item of information it seeks to withhold, and all doubts as to the applicability of the exemption must be resolved in favor of disclosure").

36. The redactions plainly cannot qualify as exempt under Exemption 5. The Second Circuit has set forth a three-prong test to determine if the deliberative process privilege applies to documents sought under FOIA. The document must be: (1) an inter-agency or intra-agency document; (2) "predecisional"; and (3) deliberative. *Tigue v. United States DOJ*, 312 F.3d 70, 76 (2d Cir. 2002). CDC has offered no evidence that the Redacted Emails qualify as exempt under the three-pronged analysis.

37. The reason that these emails plainly do not qualify for redaction under Exemption 5 is because, *inter alia*, **the withheld documents are by definition only communications between the Director of the Safety Office and outside pharmaceutical companies**. They are therefore plainly not inter-agency or intra-agency communications. Furthermore, if indeed the Safety Office is formulating and creating official government policy hand in glove with the very for-profit pharmaceutical companies it is supposed to be a watchdog over, this conduct heightens ICAN's concern and makes these documents of potentially great public importance.

38. ICAN furthermore challenges CDC's failure to provide a *Vaughn* Index. *Vaughn v. Rosen*, 484 F. 2d 820 (D.C. Cir. 1973) *cert. denied*, 415 U. S. 977 (1974). This Index must: describe each document or portion of each document which has been withheld; provide a detailed justification of the agency's grounds for non-disclosure; and correlate each exemption of FOIA

upon which the agency relies with the record or portion of the record to which the exemption purportedly applies. *Vaughn*, 484 F. 2d 820, 827.

Requested Relief

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order directing the CDC to detail the search it conducted to identify responsive documents to the FOIA Request;

c. Enter an Order directing the CDC to issue a detailed *Vaughn* Index;

d. Enter an Order directing the CDC to release unredacted copies of the responsive documents;

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

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

Dated: February 19, 2020

SIRI & GLIMSTAD LLP

Aaron Siri
200 Park Avenue
17th Floor
New York, New York 10166
Tel: (212) 532-1091

Attorneys for Plaintiff