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FREEDOM OF INFORMATION ACT APPEAL

VIA ONLINE PORTAL

May 19, 2021

Dr. Charmaine Yoest Assistant Secretary for Public Affairs / Agency Chief FOIA Officer U.S. Department of Health and Human Services Room 729H 200 Independence Avenue, S.W. Washington, D.C. 20201 FOIARequest@hhs.gov

Re: FOIA Appeal of 21-00374-FOIA (IR#0358A)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("ICAN"). On behalf of ICAN, on December 16, 2020, we requested records from the files of the Centers for Disease Control and Prevention ("CDC") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA"). The CDC assigned the request Number 21-00374-FOIA (the "FOIA Request"). In a production dated February 22, 2021, Roger Andoh, CDC/ATSDR FOIA Officer (the "CDC Officer"), redacted portions of the responsive documents pursuant to 5 U.S.C. § 552 (b)(4), (b)(5), and (b)(6) (the "Redacted Emails"). ICAN writes now to appeal these redactions.

A. <u>The FOIA Request</u>

The FOIA Request dated December 16, 2020, sought the following documents:

Individual's emails to be searched	Frank DeStefano
Date Range	January 1, 2009 through December 31, 2012
Search Terms to be run in the	@gsk OR @sanofipasteur OR
to, from, cc, or bcc fields	@merck OR @pfizer

 $(Exhibit A.)^1$

¹ All "Exhibits" referenced herein are appended to this letter.

B. The Final Response to the FOIA Request

On February 22, 2021, a final response (the "**Final Response Letter**") was provided by the CDC Officer regarding the FOIA Request and stated in relevant part:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of December 16, 2020, assigned #21-00374-FOIA, for:

"Frank DeStefeno and Pharma Communications 2009-2012 (Date Range for Record Search: From 01/01/2009 To 12/31/2012)."

We located 48 pages of responsive records (22 pages released in full; 16 pages released in part; 2 pages withheld in full). Of these 48 pages, 8 pages have been referred to the FDA for direct response to you. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) 4 and 5, 6.

(Exhibit B.)

C. Argument

CDC has improperly withheld information pursuant to Exemptions 4 and 5 (5 U.S.C. 552(b)(4) and (5)).

1. CDC has improperly withheld information pursuant to Exemption 4

Regarding redactions made pursuant to Exemption 4, CDC stated in its Final Response Letter as follows:

Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as proprietary information, and we have determined that the individual/s to whom this information pertains have a substantial commercial or financial interest in withholding it.

(Exhibit B.)

Redactions made pursuant to Exemption 4 are inappropriate because CDC has made no showing that the redacted information is commercial, financial, or confidential. CDC's Final Response makes a conclusory remark stating that the information is "commercial or financial, such as proprietary information" without providing an adequate justification for withholding the information. CDC's conclusory response gives no information by which ICAN can judge whether

or not the redacted information is confidential in nature. Therefore, CDC has failed to overturn the presumption of disclosure under FOIA, 5 U.S.C. § 552(a)(3)(A).

2. CDC has improperly withheld information pursuant to Exemption 5

Regarding redactions made pursuant to Exemption 5, CDC stated in its Final Response Letter as follows:

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 <u>deliberative process privilege</u>. 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 deliberative discussions.

(Exhibit B.)

CDC redacted statements and attachments from the Redacted Emails made by non-CDC personnel pursuant to Exemption 5. These redactions were improper because they fail to meet standards applicable to 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). Further, the redactions are not supported with the specificity and detail required under FOIA. *See Judge Rotenberng Educ. Ctr., Inc. v. United States FDA*, 376 F. Supp. 3d 47, 65 (D.D.C. 2019) (citations omitted) (holding that "[e]xemption 5 claims must be supported with specificity and [in] detail).

Regarding the first prong, if a document either originated from or was provided to an entity that is not a federal government agency, then the document is not an intra- or inter-agency document and does not fall under the protective purview of the exemption. *Sorin v. United States DOJ*, 280 F. Supp. 3d 550, 560 (S.D.N.Y. 2017). The portions of the Redacted Emails for which CDC claims Exemption 5 originated from Neal Grabowski, an associate at Genzyme Corporation. This email was sent to many non-CDC personnel. Therefore, the email does not qualify as an intra- or inter-agency record or document capable of protection through Exemption 5.

Regarding the second prong, a document is predecisional when it is "prepared in order to assist an agency decisionmaker in arriving at his decision." *Hopkins v. U.S. Dep't of Hous.* &

Urban Dev., 929 F. 2d 81, 84 (2d Cir. 1991). CDC's conclusory allegations that the Redacted Emails are "predecisional" without more are insufficient explanation to justify the redaction. *See Wilderness Soc'y v. United States DOI*, 344 F. Supp. 2d 1 (D.D.C. 2004) (finding that agency's conclusory allegations that the withheld information was predecisional was insufficient to substantiate agency's invocation of Exemption 5).

Regarding the third prong, a document is deliberative when it is "actually . . . related to the process by which policies are formulated." *Iraqi Refugee Assistance Project v. United States Dept.* of Homeland Sec., 2017 U.S. Dist. LEXIS 44563, at *11-12 (S.D.N.Y. 2017). This standard requires the agency to explain (i) "the nature of the specific deliberative process involved," (ii) "the function and significance of the documents in that process," and (iii) "the nature of the decisionmaking authority vested in the document's author and recipient." *Brennan Ctr. for Justice at NY Univ. Sch. of Law v Dept. of Homeland Sec.*, 331 F. Supp. 3d 74, 93-94 (S.D.N.Y. 2018). CDC has not provided any information to indicate how the Redacted Emails are actually related to the process by which policies are formulated, as required by the court in *Iraqi Refugee Assistance Project*.

For the foregoing reasons, Exemption 5 is not applicable, and the Redacted Emails must be produced in full.

D. <u>Appellate Request</u>

Given the foregoing, ICAN hereby appeals and requests that CDC produces the redacted materials within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact me at (212) 532-1091 or through email at foia@sirillp.com.

Very truly yours,

<u>/s/ Elizabeth A. Brehm</u> Elizabeth A. Brehm, Esq.

Enclosures

EXHIBIT A

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166 sirillp.com P: (212) 532-1091 F: (646) 417-5967

FREEDOM OF INFORMATION ACT REOUEST VIA EMAIL

December 16, 2020

Roger Andoh Freedom of Information Officer Centers for Disease Control and Prevention 1600 Clifton Road, N.E., Building 57, Room MS D-54 Atlanta, Georgia 30333 Fax: (404) 235-1852 FOIARequests@cdc.gov

Re: Frank DeStefano Communications January 1, 2009 through December 31, 2012 (IR#0358A)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, please provide the following records to <u>foia@sirillp.com</u> in electronic form:

Individual's emails to be searched	Frank DeStefano
Date Range	January 1, 2009 through December 31, 2012
Search Terms to be run in the to, from, cc,	@gsk OR @sanofipasteur OR @merck OR
or bcc fields	@pfizer

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Elizabeth A. Brehm Elizabeth A. Brehm, Esq.

EXHIBIT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES



Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta GA 30333 February 22, 2021

Elizabeth Brehm Siri & Glimstad 200 Park Ave 17th Floor New York, NY 10166 Via email: foia@sirillp.com

Dear Ms. Brehm:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of December 16, 2020, assigned #21-00374-FOIA, for:

"Frank DeStefeno and Pharma Communications 2009-2012 (Date Range for Record Search: From 01/01/2009 To 12/31/2012)."

We located 48 pages of responsive records (22 pages released in full; 16 pages released in part; 2 pages withheld in full). Of these 48 pages, 8 pages have been referred to the FDA for direct response to you. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) 4 and 5, 6.

EXEMPTION 4

Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as proprietary information, and we have determined that the individual/s to whom this information pertains have a substantial commercial or financial interest in withholding it.

EXEMPTION 5

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 <u>deliberative process privilege</u>. 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 deliberative discussions.

EXEMPTION 6

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 home addresses and emails. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

Page 2 - Elizabeth Brehm

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201.You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by May 23, 2021.

Sincerely,

Roger Andoh CDC/ATSDR FOIA Officer Office of the Chief Operating Officer (770) 488-6399 Fax: (404) 235-1852

Enclosures

21-00374-FOIA