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CDC FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL May 8, 2023

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
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request #22-02077-FOIA (IR#0828B)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on August 17, 2022, we submitted a request for records ("**FOIA Request**") 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**"). On March 16, 2023, Roger Andoh, CDC/ATSDR FOIA Officer, responded to the FOIA Request ("**Final Response**"). ICAN writes now to appeal the Final Response.

A. FOIA Request #22-02077-FOIA (IR#0828B)

On August 17, 2022, ICAN submitted a request to CDC for the following:

1. Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines manufactured; and (2) the total number of units and/or doses in each such lot.

2. Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines distributed/shipped; (2) the destinations of those distributions/shipments; (3) the dates of those distributions/shipments; and (4) the total number of distributed/shipped units and/or doses from each such lot.

3. Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines administered; (2)

> the dates of those administrations; (3) the location of those administrations; and (4) the total number of administrated units and/or doses from each such lot.

(**Attachment 1**.)[1]

The request was acknowledged and assigned FOIA Request #22-02077-FOIA on August 18, 2022. (**Attachment 2**.)

B. CDC's Final Response

On March 16, 2023, CDC issued a Final Response letter. The letter stated in relevant part,

> We located an Excel spreadsheet of responsive records withheld in part. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption 4. The foreseeable harm standard was considered when applying these redactions.
>
> Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information.

(**Attachment 3**.)

C. Argument

CDC has not properly demonstrated that the withheld records fall under the scope of Exemption 4. "An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "[C]onclusory assertions, without any additional description of the contents of the redacted information or reasons for non-disclosure, are insufficient to show that Exemption 4 was appropriately invoked." *Comptel v. FCC*, 945 F. Supp. 2d 48, 57 (D.D.C. 2013).

Exemption 4 prevents disclosure of "trade secrets and commercial or financial information obtained from a person and privileged or confidential[.]" 5 U.S.C. § 552(b)(4). Exemption 4 applies to two categories of information. *Nw. Coal. for Alts. to Pesticides v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996). The first category, "trade secrets," applies to "'a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or

[1] All "Attachments" referenced herein are appended to this letter.

substantial effort.'" *Id.* at 201-202 (quoting *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983)).

The second category is "[i]nformation that (1) is financial or commercial; (2) was obtained from a person; and (3) is privileged or confidential[.]" *Id.* at 202. The Supreme Court recently held, "where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019). An agency must reasonably demonstrate that private owner of the records treats the information as "confidential." *See Ruston v. DOJ*, 521 F. Supp. 2d 18, 18-21 (D.D.C 2007) (court held the agency reasonably demonstrated the records were actually treated as confidential because the agency acquired statements and further proof of confidentiality from the private owner of the records).

Furthermore, "[c]ommercial information is 'confidential' for purposes of FOIA Exemption 4 if disclosure is likely to cause substantial harm to the competitive position of the person from whom the information was obtained." *Nw. Coal. for Alts. to Pesticides*, 941 F. Supp. at 202. Provided the narrow construction given to FOIA exemptions, courts have cautioned that "[n]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4." *Public Citizen Health Research Group v. FDA*, 704 F.2d at 1290. "Exemption 4 does not guard against mere embarrassment in the marketplace or reputational injury." *United Techs. Corp., Pratt & Whitney Div. v. DOD*, 601 F.3d 557, 563-64 (D.C. Cir. 2010) (court rejected claims that the company would suffer competitive harms because "their competition will use the documents to discredit them in the eyes of current and potential customers" and their "reputation will suffer as a result," and the court determined "Exemption 4 does not protect against this species of harm").

Lot numbers are not trade secrets or financial or commercial information and are made public in numerous ways by, among others, regulators and vaccine administrators.

Therefore, for these reasons, CDC has failed to prove the applicability of Exemption 4. *American Civil Liberties Union*, 628 F.3d at 619. ICAN requests CDC either prove the applicability of Exemption 4 or provide an unredacted copy of the withheld records.

D. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Request be produced within 20 days of this appeal. Thank you for your time and attention

to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com.**

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin M. Farnsworth, Esq.
Marc A. Dudley, Esq.

Enclosures

Attachment 1

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

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CDC FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL August 17, 2022

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

Re: All Pfizer/BioNTech COVID-19 Vaccines Lot Number Information (IR#0828B)

Dear Sir or Madam:

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

1. **Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines manufactured; and (2) the total number of units and/or doses in each such lot.**

2. **Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines distributed/shipped; (2) the destinations of those distributions/shipments; (3) the dates of those distributions/shipments; and (4) the total number of distributed/shipped units and/or doses from each such lot.**

3. **Documents sufficient to identify: (1) drug product lot numbers for all Pfizer/BioNTech COVID-19 vaccines administered; (2) the dates of those administrations; (3) the location of those administrations; and (4) the total number of administrated units and/or doses from each such lot.**

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 news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Exhibit A**.) As part of its mission, ICAN actively investigates and disseminates information regarding vaccine

safety issues for free, including through its website,[1] a weekly health news and talk show,[2] and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

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 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 take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

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

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin M. Farnsworth Esq.

[1] https://www.icandecide.org/.

[2] https://thehighwire.com/.

Exhibit A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022

Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed said Catharine Layton sign the above statement this 3 day of May (month), 2022

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024

Attachment 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

August 18, 2022

Aaron Siri
Siri & Glimstad LLP
745 Fifth Ave.
Suite 500
New York, NY 10151
Via email: foia@sirillp.com

Dear Mr.Siri:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated August 17, 2022. Your request assigned number is 22-02077-FOIA, and it has been placed in our complex processing queue.

Extension of Time
In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:
x
xWe reasonably expect to receive and review voluminous records in response to your request.
x We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request LaShonda Schofield at 770-488-6241 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) 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.

Fees and Fee Waiversx

You requested that we waive fees associated with processing your request. Your request is granted

Fee Categoryx

Because you are considered an “Other requester” you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

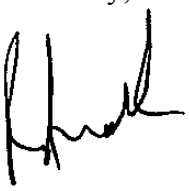
Cut-off-date

If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6241 or via email at hur7@cdc.gov.

We reasonably anticipate that you should receive documents by December 12, 2022. Please know that this date roughly estimates how long it will take the Agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



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

22-02077-FOIA

Attachment 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

March 16, 2023

Aaron Siri
Siri & Glimstad, LLP
745 Fifth Ave.
Suite 500
New York, NY 10151
Via email: foia@sirillp.com

Dear Mr. Siri:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of August 17, 2022, assigned #22-02077-FOIA, for (see attached).

We located an Excel spreadsheet of responsive records withheld in part. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption 4. The foreseeable harm standard was considered when applying these redactions. Please see the link below for the records (expires in 180 days).

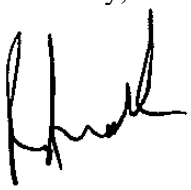
https://centersfordiseasecontrol.sharefile.com/d-s5cd1219d986f448aace9bf4c2c3d57df

EXEMPTION 4
Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information.

You may contact our FOIA Public Liaison at 770-488-6246 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 to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by June 14, 2023.

Sincerely,



Roger Andoh
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Enclosures

22-02077-FOIA