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CDC FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL May 17, 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 #22-02076-FOIA (IR#0828A)*

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 February 21, 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 #22-02076-FOIA (IR#0828A)

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 Moderna 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 Moderna 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 Moderna 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 #22-02076-FOIA on August 18, 2022. (**Attachment 2**.)

B. CDC's Final Response

On February 21, 2023, CDC issued a Final Response letter. The letter stated in relevant part,

> We located an Excel spreadsheet of responsive records released 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

In order to lawfully deny this FOIA Request, CDC "…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). To carry this burden, CDC must demonstrate that it "…reasonably foresees that disclosure would harm an interest protected by an exemption" or that disclosure is "prohibited by law." 5 U.S.C. § 552(a)(8)(A). For the reasons set forth below, CDC failed to prove that Exemption 4 properly applied to this FOIA Request.

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). This exemption 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 Exemption 4 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 Exemption 4 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. "[I]nformation is commercial under this exemption if, in and of itself, it serves a commercial function or is of a commercial nature." *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 38 (D.C. Cir. 2002).

For example, "records that actually reveal basic commercial operations, such as sales statistics, profits and losses and inventories, or relate to the income-producing aspects of a business" fall within the scope of commercial information. *See Public Citizen Health Research Group*, 704 F.2d, at 1290. Moreover, commercial or financial information is only "confidential" for the purposes of Exemption 4 when it is "both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019).

An agency must reasonably demonstrate that the 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). "Conclusory and generalized allegations of substantial competitive harm, of course, are unacceptable and cannot support an agency's decision to withhold requested documents." *Public Citizen Health Research Group,* 704 F.2d at 1291.

However, 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. Regarding Exemption 4, an agency satisfies the foreseeable harm requirement by demonstrating "foreseeable commercial or financial harm to the submitter upon release of the contested information." *Seife v. United States Food & Drug Admin.*, 43 F.4th 231, 241-42 (2d Cir. 2022).

Here, CDC failed to prove the applicability of Exemption 4 to the withheld information for two reasons.

First, CDC's Final Response did not explain how the withheld information qualifies as a trade secret or confidential commercial or financial information. *Civil Liberties Union*, 628 F.3d at 619; *Nw. Coal. for Alts. to Pesticides*, 941 F. Supp. at 202. In this instance, CDC completely withheld the "provide_pin, "lot_number", "doses_shipped", "doses_shipped", and "#ofShipmentsbyLotbyDose#" columns of the provided spreadsheet, yet failed to explain how this information qualifies as confidential information. Instead, CDC's Final Response, simply states,

> 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**.)

On these facts, CDC has neither demonstrated that "…the private owner of the records treats the information as confidential", nor has it shown that the government has provided any "assurances of privacy" to the individual and/or entity that provided the records to CDC. *See Food Mktg. Inst*., 139 S. Ct. at 2366. Moreover, CDC's Final Response did not provide any information as to how it is reasonably foreseeable that the release of the withheld materials would cause commercial or financial harm to the submitter upon release. *Seife*, 43 F.4th at 241-42.

Second, it is, at best, unclear how CDC determined that the requested information is confidential. Notably, drug product lot numbers are already in the public domain because they are disclosed on the distributed products themselves. Further, ICAN is unaware of (and CDC has not claimed) any lawful FOIA exemption explicitly prohibiting the disclosure of lot numbers, the number of doses contained in each lot, doses shipped, and/or any similarly related information. As such, it's highly unlikely the redacted information qualifies for Exemption 4 protection.

Finally, and notably, as confirming evidence that the heretofore withheld information is not treated as confidential and is made public, CDC has produced this same type of data in unredacted form in response to other FOIA requests. For example, in CDC's production for FOIA request #22-01271, it produced the "lot_number[s]," "Doses_shipped," "#ofShipmentsbyLotbyDose#," and "DosesByLot" relating to Pfizer's COVID-19 vaccines unredacted – similar categories of information CDC redacted pursuant to Exemption 4 in the present case. As another example, in CDC's production of FOIA request #22-01963, it provided the following combination of information, among others, and the production contained 426,937 rows of data, one of which is included in the example below:

PROVIDER_PIN	PROVIDER_NAME	CITY_SHP	STATE_SHP	ZIPCODE_SHP	LOT_NUMBER	DOSES_SHIPPED
ALA 01208	LILLIAN PHARMACY	LILLIAN	AL	36549-4053	30135BA	1170.000

This production also contained a column titled "VAX MANUFACTURER" indicating that this database of information contains similar information for each COVID-19 vaccine manufacturer, including Moderna. CDC also recently agreed to provide an unredacted supplemental production in response to both FOIA request numbers 22-01273-FOIA and 22-01274-FOIA, both seeking Moderna lot and shipping information.

The unredacted information released in the two productions above, and soon to be released in the third, demonstrates that such information is not customarily "confidential," as defined by Exemption 4. Meaning, Moderna does not actually treat such information as confidential and/or the information was provided without government assurances of privacy. *Food Mktg. Inst.*, 139 S. Ct. at 2366. Therefore, it seems CDC is not able to adequately demonstrate why information provided by Moderna is "confidential" under Exemption 4.

For these reasons, CDC's failure to carry its statutory burden of proving that Exemption 4 applies to this FOIA Request requires the prompt release of an unredacted copy of the requested 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.

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 Moderna COVID-19 Vaccines Lot Number Information (IR#0828A)

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 Moderna 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 Moderna 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 Moderna 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/.

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.

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 22-02076-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:

☐ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.
x We 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.
☐ We reasonably expect that records located would contain confidential commercial information. We are required to notify submitters of confidential information if their information is requested through a FOIA request. Submitters have 10 working days to object to the release of their information.

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 Waivers

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

Fee Category

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).

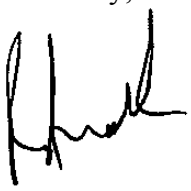
Cut-off-date

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

22-02076-FOIA

Attachment 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

February 21, 2023

Aaron Siri
Siri & Glimstad LLP
745 Fifth Avenue
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 #22-02076-FOIA, for "[0828A] 1. Documents sufficient to identify: (1) drug product lot numbers for all Moderna 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 Moderna 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; and

3. Documents sufficient to identify: (1) drug product lot numbers for all Moderna 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 located an Excel spreadsheet of responsive records released in part. After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption 5. The foreseeable harm standard was considered when applying these redactions. Please find below a link to the records (the link expires in 180 days): https://centersfordiseasecontrol.sharefile.com/d-sca3ac0c1dc304e53b05d3236594f3a3a

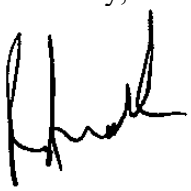
EXEMPTION 4

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 May 22, 2023.

Sincerely,



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

Enclosures

22-02076-FOIA