Exhibit 101

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CDC FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL August 8, 2022

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 # 22-01273-FOIA (IR#0733A)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on March 30, 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 June 27, 2022, Roger Andoh, CDC/ATSDR FOIA Officer ("**CDC Officer**") responded to the FOIA Request ("**Final Response**"). ICAN writes now to appeal the Final Response.

A. FOIA Request # 22-01273-FOIA (IR#0733A)

On March 30, 2022, ICAN submitted a request to the CDC for the following documents:

> **A. Documents sufficient to identify: (1) drug product lot numbers for all Moderna COVID-19 vaccines manufactured in the United States; and (2) the total number of units and/or doses in each such lot.**
>
> **B. Documents sufficient to identify: (1) drug product lot numbers for all Moderna vaccines distributed in the United States; and (2) the total number of distributed units and/or doses from each such lot.**

> **C. Documents sufficient to identify: (1) drug product lot numbers for all Moderna vaccines administered in the United States; and (2) the total number of administrated units and/or doses from each such lot.**

(**Exhibit 1**.)[1]

On April 1, 2022, CDC acknowledged the FOIA request and assigned FOIA case # 22-01273-FOIA. (**Exhibit 2**.)

B. CDC's Final Response

On June 27, 2022, the CDC issued a final response letter. The letter stated in part,

> **We located one responsive record. After a careful review of this record, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption b(4). The foreseeable harm standard was considered when applying these redactions. . . . The information withheld is commercial or financial information that reveals competitive details, and we have determined that the entity to whom this information pertains has a substantial commercial or financial interest in withholding it.**

(**Exhibit 3**.)

C. Argument

CDC has improperly withheld records under FOIA Exemption 4 and has failed to conduct an adequate search. For the reasons set forth below, ICAN appeals CDC's Final Response.

1. The CDC Improperly Withheld Records Under FOIA Exemption 4

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). 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 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 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

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

"[i]nformation that (1) is financial or commercial; (2) was obtained from a person; and (3) is privileged or confidential[.]" *Id.* at 202. "Commercial 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." *Id.* 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).

CDC has failed to prove the applicability of Exemption 4 because CDC did not explain how the redacted information qualifies as confidential commercial or financial information, nor how the disclosure is likely to cause substantial harm. *American Civil Liberties Union*, 628 F.3d at 619; *Nw. Coal. For Alts. To Pesticides*, 941 F. Supp. At 202. In this instance, CDC redacts nearly all responsive records using exemption 4. The responsive records include columns of records which are titled "lot_number", "DosesByLot", "doses_shipped" or "#ofShipmentsbyLotbyDose#," but the rows of data in each column are entirely redacted under Exemption 4. In the CDC's Final Response, it stated,

> **The information withheld is commercial or financial information that reveals competitive details, and we have determined that the entity to whom this information pertains has a substantial commercial or financial interest in withholding it.**

CDC did not adequately demonstrate that the private owner of the records treats the information as confidential. Further CDC has not demonstrated that the government has provided any assurances of privacy for the records. Thus, according to the Supreme Court, CDC has improperly withheld responsive records under Exemption 4. *Food Mktg. Inst.*, 139 S. Ct. at 2366.

Further, based upon the titles of the redacted rows, it is unclear how such information could likely cause substantial harm to the private owner. Lot numbers are already in the public domain because they are disclosed on the distributed products. Further, ICAN is unaware of any exemption that would prohibit the disclosure of lot numbers, the number of doses contain in each lot, doses shipped or any related information. Thus, it's highly unlikely the redacted information qualifies as privileged and confidential. *Id*.

Lastly, it remains unclear whether CDC segregated disclosable records as required by law. FOIA requests often seeks a mixture of exempt and non-exempt records. "For such a request, an agency must segregate the non-exempt information from the exempt information, disclosing the former but not the latter. *Elec. Privacy Info. Ctr. v. IRS*, 910 F.3d 1232, 1237 (D.C. Cir. 2018); *See* 5 U.S.C. § 552(b) ("Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this

subsection"). "To withhold records, then, the agency must establish that an exemption applies and, for mixed requests, must still disclose 'all reasonably segregable, nonexempt portions of the requested record(s).'" *Elec. Privacy Info. Ctr.,* 910 F.3d at 1237 (*quoting Assassination Archives & Research Ctr. v. CIA*, 334 F.3d 55, 57-58 (D.C. Cir. 2003)). CDC's Final Response make no mention of the segregability of the redacted records. In this instance, even if some of the redacted rows were properly exempt, the others must be immediately released.

2. The CDC Failed to Conduct an Adequate Search

CDC has failed to conduct an adequate search of the requested records. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. E.P.A.*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dep't. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was reasonably calculated to uncover all relevant documents." *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (quoting *Valencia-Lucena v. U.S. Coast Guard,* 180 F.3d 321, 325 (D.C. Cir. 1999)) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A*., 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At minimum, the agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

CDC's search was inadequate because it did not specify what records were searched, by whom, and through what process. *Steinberg*, 23 F.3d 552. The redacted document provided, even if completely unredacted, is not fully responsive to the entire request. Therefore, CDC did not fulfill its obligations under FOIA of demonstrating beyond material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena,* 180 F.3d at 325.

D. <u>Appellate Request</u>

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Requests 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 Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

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CDC FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL March 30, 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: Moderna Drug Product Lot Numbers and Doses Manufactured, Distributed and Administered (IR#0733A)

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:

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

B. Documents sufficient to identify: (1) drug product lot numbers for all Moderna vaccines distributed in the United States; and (2) the total number of distributed units and/or doses from each such lot.

C. Documents sufficient to identify: (1) drug product lot numbers for all Moderna vaccines administered in the United States; and (2) 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. 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.

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 take further 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 2

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

April 1, 2022

Aaron Siri
Siri & Glimstad LLP
200 Park Ave
17th Floor
New York, NY 10166
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 attached Freedom of Information Act (FOIA) request dated March 30, 2022. Your request assigned number is 22-01273-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.
- We reasonably expect to receive and review voluminous records in response to 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 Yuliya Scott at tkz7@cdc.gov 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, however we may charge reduced fees instead of waiving all fees. If we decide to charge reduced fees you will be notified.

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

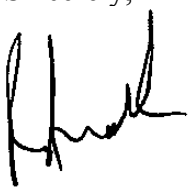
for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

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 Yuliya Scott at tkz7@cdcc.gov.

Sincerely,



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

22-01273-FOIA

Exhibit 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

June 27, 2022

Aaron Siri
Siri & Glimstad LLP
200 Park Ave
17th Floor
New York, NY 10166
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 March 30, 2022, assigned #22-01273-FOIA.

We located one responsive record. After a careful review of this record, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption b(4). The foreseeable harm standard was considered when applying these redactions. The responsive record can be downloaded in its native Excel format from the following link: https://centersfordiseasecontrol.sharefile.com/d-s92fc52ee38a24e11a3edd51bd2c7f0e0

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 that reveals competitive details, and we have determined that the entity to whom this information pertains has a substantial commercial or financial interest in withholding it.

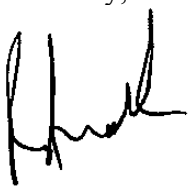
Your request has also been referred to the Department of Health and Human Services for their review and direct response to you with any potential responsive records. You may inquire about the status of your request with them at the following address:

Department of Health and Human Services
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201
Send general questions to: FOIARequest@hhs.gov
Phone: 202-690-7453
Fax: 202-690-8320
FOIA Officer: Brandon Gaylord

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 October 24, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
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Enclosures

22-01273-FOIA