UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

Civil Action No.

CENTERS FOR DISEASE CONTROL AND PREVENTION AND U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendant.

COMPLAINT

Plaintiff Informed Consent Action Network ("ICAN" or "Plaintiff") brings this action against Defendants Centers for Disease Control and Prevention ("CDC" or "Defendant") and U.S. Department of Health and Human Services ("HHS" or "Defendant") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). As grounds therefor, Plaintiff alleges as follows:

JURISDICTION AND VENUE

The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and
28 U.S.C. § 1331.

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705. 4. Defendant CDC is an agency within the Executive Branch of the United States Government, organized within the U.S. Department of Health and Human Services. The CDC is an agency within the meaning of 5 U.S.C. § 552(f).

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

STATEMENT OF FACTS

I. <u>HHS Case No. 2022-00228-A-PHS and FOIA Request # 22-01273-FOIA (IR#0733A)</u>

6. On March 30, 2022, Plaintiff sent a FOIA request to CDC, seeking copies of the

following:

- 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 101 at 7.)

7. On June 27, 2022, the CDC issued a final response, produced some responsive

records, and withheld some records pursuant to 5 U.S.C. § 552(b)(4) ("Exemption 4"). (Exhibit

101 at 13.)

8. On August 8, 2022, Plaintiff appealed the CDC's final response challenging the adequacy of its search, and its improper use of Exemption 4 to withhold responsive records.

(Exhibit 101 at 2-5.)

9. On August 9, 2022, HHS acknowledged the appeal, assigned it Case No. 2022-

00228-A-PHS, and stated, in part, the following:

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue.

(Exhibit 102.)

- 10. In violation of the time limits prescribed by 5 U.S.C. § 552(a)(6)(A)(ii) and 5
- U.S.C. § 552(a)(6)(B)(i), as of the date of this Complaint, HHS has failed to make a determination

with respect to Plaintiff's appeal.

II. HHS Case No. 2022-00209-A-PHS & FOIA Request # 22-01274-FOIA (IR#0734A)

11. On March 30, 2022, Plaintiff also sent the following FOIA request to the CDC,

seeking access to the following:

- A. Documents sufficient to identify: (1) each state or U.S. territory to which all or part of any Moderna COVID-19 vaccine lot was shipped; and (2) the total number of units and/or doses of each individual Moderna COVID-19 vaccine shipped to each such state or U.S. territory.
- B. Documents sufficient to identify: (1) the primary end- user destination to which all or part of any Moderna COVID-19 vaccine lot was shipped; and (2) the total number of units and/or doses of each individual Moderna COVID-19 vaccine lot shipped to each such primary end-user destination.

C. Documents sufficient to identify how much of each Moderna COVID-19 vaccine lot is distributed in the U.S. and how much of the same lot is distributed internationally.

(Exhibit 103 at 7.)

12. On June 27, 2022, the CDC issued a final response, produced some responsive

records, and withheld some records pursuant to Exemption 4. (Exhibit 103 at 13.)

13. On July 18, 2022, Plaintiff appealed CDC's final response, challenging the

adequacy of its search and its improper use of Exemption 4 to withhold responsive records.

(Exhibit 103 at 2-5.)

14. On July 18, 2022, HHS acknowledged the appeal, assigned it Case No. 2022-

00209-A-PHS, and stated, in part, the following:

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue.

(Exhibit 104.)

15. In violation of the time limits prescribed by 5 U.S.C. § 552(a)(6)(A)(ii) and 5

U.S.C. § 552(a)(6)(B)(i), as of the date of this Complaint, HHS has failed to make a determination

with respect to Plaintiff's appeal.

<u>COUNT I</u> <u>FAILURE TO MAKE DETERMINATION BY REQUIRED DEADLINE</u> <u>(VIOLATION OF FOIA, 5 U.S.C. § 552)</u>

16. Plaintiff realleges paragraphs 1 through 15 as if fully stated herein.

17. As to Case No. 2022-00228-A-PHS, Defendant was required to make a determination on Plaintiff's appeal by September 21, 2022.

18. As to Case No. 2022-00209-A-PHS, Defendant was required to make a determination on Plaintiff's appeal by August 29, 2022.

19. Defendant failed to make these determinations on Plaintiff's appeals within the time limits set forth by FOIA; therefore, Plaintiff is deemed to have exhausted its administrative remedies. 5 U.S.C. 552(a)(6)(A)(ii); 5 U.S.C. 552(a)(6)(B)(i) and 5 U.S.C. 552(a)(6)(C)(i).

20. Defendant is in violation of FOIA.

<u>COUNT II</u> <u>FAILURE TO ESTABLISH ADEQUACY OF SEARCH</u> <u>(VIOLATION OF FOIA, 5 U.S.C. § 552)</u>

21. Plaintiff realleges paragraphs 1 through 20 as if fully stated herein.

22. For both Case No. 2022-00228-A-PHS and Case No. 2022-00209-A-PHS, Defendant has failed to establish that it adequately searched for responsive records despite Plaintiff's challenge to same in Plaintiff's appeals.

23. Defendant is in violation of FOIA.

<u>COUNT III</u> <u>IMPROPER REDACTIONS AND/OR WITHOLDING OF RECORDS</u> (VIOLATION OF FOIA, 5 U.S.C. § 552)

24. Plaintiff realleges paragraphs 1 through 23 as if fully stated herein.

25. For both Case No. 2022-00228-A-PHS and Case No. 2022-00209-A-PHS, Defendant has failed to establish the validity of its claimed exemption despite Plaintiff challenging the same in Plaintiff's appeals.

26. Defendant is in violation of FOIA.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Declare that Defendant's continued delay in processing Plaintiff's FOIA appeals is unlawful under FOIA;

b. Declare that Defendant has failed to conduct and adequate search for responsive records as required by FOIA;

c. Declare that Defendant improperly withheld responsive records under Exemption4;

d. Order Defendant to conduct searches for any and all records responsive to Plaintiff's FOIA requests and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA requests;

e. Order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA requests and a *Vaughn* index of any responsive records withheld under any claimed exemptions;

f. Enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA requests;

g. Maintain jurisdiction over this action until Defendant complies with FOIA and all orders of this Court;

h. Grant Plaintiff an award of attorneys' fees and other litigation costs reasonably

incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

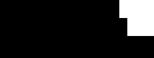
i. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: November 2, 2022

SIRI & GLIMSTAD LLP

/s/ Aaron Siri

Aaron Siri, Bar No. 4321790 Elizabeth A. Brehm, NY Bar No. 4660353 (pro hac vice to be filed) Colin M. Farnsworth, OR Bar No. 213351 (pro hac vice to be filed) 745 Fifth Ave, Suite 500 New York, NY 10151 (212) 532-1091



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