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8
9 **IN THE UNITED STATES DISTRICT COURT**
10 **FOR THE DISTRICT OF ARIZONA**

11 Informed Consent Action Network,
12 Plaintiff,
13 v.
14 National Institutes of Health,
15 Defendant.

CV-20-01277-JJT

**DEFENDANT'S ANSWER AND
AFFIRMATIVE DEFENSES TO
PLAINTIFF'S COMPLAINT FOR
DECLARATORY AND INJUNCTIVE
RELIEF**

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17 **ANSWER TO COMPLAINT¹ AND AFFIRMATIVE DEFENSES**

18 Pursuant to Rule 8, Federal Rules of Civil Procedure, Defendant National Institutes
19 of Health ("NIH"), by and through its attorneys, hereby responds to Plaintiff Informed
20 Consent Action Network as follows:

21 **Introduction**

22 1. The allegations contained in Paragraph 1 do not set forth a claim for relief or
23 aver facts in support of a claim to which a response is required. To the extent that a
24 response is required, Defendant denies the allegations in Paragraph 1.

25 2. Defendant admits that the National Institute of Allergy and Infectious
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27 ¹ For ease of reference, Defendant's Answer generally replicates the headings contained in
28 the Complaint. Although Defendant believes that no response is required to such headings,
to the extent a response is deemed required and to the extent those headings and titles may
be construed to contain factual allegations, those allegations are denied.

1 Diseases (“NIAID”) is an institute within NIH and that Dr. Anthony S. Fauci is NIAID’s
 2 Director. Defendant further admits that NIAID has been funding and leading the
 3 development of mRNA-1273, the first vaccine for COVID-19 to enter into clinical trials.
 4 The remaining allegations of Paragraph 2 do not set forth a claim for relief or aver facts in
 5 support of a claim to which a response is required. To the extent that a response is required,
 6 Defendant denies those remaining allegations.

7 3. The allegations contained in Paragraph 3 consist of Plaintiff’s
 8 characterization of itself and do not set forth a claim or aver facts in support of a claim to
 9 which a response is required. To the extent that a response is required, Defendant lacks
 10 knowledge or sufficient information to form a belief as to the allegations, and therefore
 11 denies the allegations.

12 4. Defendant admits only that Plaintiff submitted the 13 FOIA requests to NIH,
 13 as detailed below:

REQUEST NUMBER	Dated	Request	Citation
Request 53821	3/27/20	Copies of all and each Employee Invention Report related to any vaccine or therapeutic for COVID-19.	Exhibit A to Plaintiff’s Complaint, Dkt. 1-1 at 3-4
Request 53822	3/27/20	Copies of any and all royalty or licensing agreements related to any vaccine or therapeutic for COVID-19.	Exhibit B to Plaintiff’s Complaint, Dkt. 1-1 at 6-7
Request 53826	3/27/20	A copy of the page of any patent application filed with regard to the mRNA-1273 vaccine which lists the inventors.	Exhibit C to Plaintiff’s Complaint, Dkt. 1-1 at 9-10
Request 53963	4/9/20	All emails sent or received by Anthony Fauci between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body,	Exhibit D to Plaintiff’s Complaint, Dkt. 1-1 at

1		subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	12-13
2	Request 53962	All emails sent or received by Barney Graham between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit E to Plaintiff's Complaint, Dkt. 1-1 at 15-16
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6	Request 53961	All emails sent or received by Kizzmekia Corbett between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit F to Plaintiff's Complaint, Dkt. 1-1 at 18-19
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11	Request 53958	All emails sent or received by Michael Gordon Joyce between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit G to Plaintiff's Complaint, Dkt. 1-1 at 21-22
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15	Request 53960	All emails sent or received by Masaru Kanekiyo between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit H to Plaintiff's Complaint, Dkt. 1-1 at 24-25
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19	Request 53959	All emails sent or received by Olubukola Mary Abisola Abiona between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit I to Plaintiff's Complaint, Dkt. 1-1 at 27-28
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24	Request 54105	All emails sent or received by Hadi Yassine between November 1, 2019 and the present that include the term Moderna or mRNA-1273 in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit J to Plaintiff's Complaint, Dkt. 1-1 at 30-31
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28	Request 54106	All emails sent or received by Anthony Fauci between November 1, 2019 and the present that	Exhibit K to Plaintiff's

		include the term SARS-CoV, COVID, COVID-19 or coronavirus in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Complaint, Dkt. 1-1 at 33-34
Request 54107	4/29/20	All emails sent or received by Barney Graham between November 1, 2019 and the present that include the term SARS-CoV, COVID, COVID-19 or coronavirus in any portion of the email, including the body, subject, metadata, sender line, or recipient line of the email, or any attachment to the email.	Exhibit L to Plaintiff's Complaint, Dkt. 1-1 at 36-37
Request 54464	5/22/20	All safety and efficacy data and information regarding mRNA-1273, including from the Phase I clinical trial of this experimental vaccine conducted by the National Institute of Allergy and Infectious Diseases.	Exhibit M to Plaintiff's Complaint, Dkt. 1-1 at 39-40

Defendant respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a complete and accurate description of their contents. Defendant further admits that NIH granted expedited processing for Request 54464. NIH denies the allegation that NIH failed to further respond to Plaintiff's requests. In addition, Defendant lacks knowledge or sufficient information to form a belief as to the allegations pertaining to Plaintiff's mission or acts pertaining to inquiries it received, and therefore denies those allegations.

5. Defendant admits that it has not yet provided a final determination letter or produced any documents in response to Plaintiff's 13 FOIA requests, as it is still processing those requests. The remaining allegations contained in Paragraph 5 consist of Plaintiff's characterization of its FOIA requests, its motive in bringing this action, and its conclusions of law, to which no response is required. To the extent that a response is required, Defendant denies those allegations.

Parties

6. The allegations contained in Paragraph 6 contain Plaintiff's characterization of itself. Defendant lacks knowledge or sufficient information to form a belief as to the allegations, and therefore denies the allegations.

1 allegations, and therefore denies the allegations.

2 17. The allegations contained in Paragraph 17 contain legal conclusions and do
3 not set forth a claim or aver facts in support of a claim to which a response is required. To
4 the extent that a response is required, Defendant lacks knowledge or sufficient information
5 to form a belief as to the allegations, and therefore denies the allegations.

6 **I. The FOIA Requests**

7 18. Admit.

8 19. Defendant admits that Plaintiff submitted each of the listed FOIA requests to
9 NIH and respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a complete
10 and accurate description of their contents. However, Defendant denies that Requests
11 53963, 53962, 53961, 53958, 53960, 53959 and 54105 were dated April 10, 2020.

12 20. Defendant admits that Plaintiff submitted each of the listed FOIA requests to
13 NIH and respectfully refers the Court to the request letters (Dkt. 1-1 at 3-40) for a complete
14 and accurate description of their contents. However, Defendant denies that Requests 54106
15 and 54107 were dated May 5, 2020.

16 21. Defendant admits only that Plaintiff submitted Request 54464 on May 22,
17 2020 and Plaintiff requested expedited processing for this request. Plaintiff's
18 characterization of the requested information as "critical" and "specific" calls for legal
19 conclusions, and Defendant therefore denies these allegations.

20 22. The allegations contained in Paragraph 22 consist of Plaintiff's conclusions
21 of law, to which no response is required. To the extent that a response is required,
22 Defendant denies the allegations.

23 23. The allegations contained in Paragraph 22 consist of Plaintiff's conclusions
24 of law, to which no response is required. To the extent that a response is required,
25 Defendant denies the allegations.

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1 **II. NIH (Allegedly) Fails to Properly Respond or Produce Any Documents²**

2 24. The allegations contained in Paragraph 24 consist of Plaintiff's conclusions
3 of law, to which no response is required. To the extent that a response is required,
4 Defendant denies the allegations.

5 25. Defendant admits only that it sent Plaintiff correspondence regarding each of
6 the listed FOIA requests and respectfully refers the Court to the correspondence (Dkt. 1-1
7 at 42-68) for a complete and accurate description of their contents. Defendant denies all
8 other allegations, including any characterizations as to the sufficiency of the
9 correspondence, in Paragraph 25.

10 26. Defendant admits only that it sent Plaintiff correspondence regarding
11 Request 54464 and respectfully refers the Court to the correspondence (Dkt. 1-1 at 67-68)
12 for a complete and accurate description of its contents. Defendant denies all other
13 allegations, including any characterization of NIH's interpretation of the request, in
14 Paragraph 26.

15 27. Admit.

16 28. The allegations contained in Paragraph 28 consist of Plaintiff's conclusions
17 of law, to which no response is required. To the extent that a response is required,
18 Defendant denies the allegations.

19 29. The allegations contained in Paragraph 29 consist of Plaintiff's conclusions
20 of law, to which no response is required. To the extent that a response is required,
21 Defendant denies the allegations.

22 30. The allegations contained in Paragraph 30 consist of Plaintiff's conclusions
23 of law, to which no response is required. To the extent that a response is required,
24 Defendant denies the allegations.

25 31. The allegations contained in Paragraph 31 consist of Plaintiff's conclusions
26 of law, to which no response is required. To the extent that a response is required,

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28 ² This header is an argumentative and conclusory statement, and Defendant denies it as such.

1 Defendant denies the allegations.

2 **REQUESTED RELIEF**

3 The remainder of the Complaint consists of Plaintiff's Prayer for Relief, to which
4 no response is required. To the extent that a response is required, Defendant incorporate
5 by reference the responses to all preceding paragraphs, and denies the allegations in the
6 Prayer for Relief, and denies that Plaintiff is entitled to any of the relief requested in
7 Paragraphs 1 through 31, or to any relief whatsoever from the Defendant.

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9 **AFFIRMATIVE DEFENSES**

10 **FIRST AFFIRMATIVE DEFENSE**

11 1. Plaintiff's Complaint fails to state a claim upon which relief may be granted.

12 **SECOND AFFIRMATIVE DEFENSE**

13 2. Any information that Defendant have withheld, or will withhold, in response
14 to Plaintiff's FOIA request may be exempt in whole or in part from public disclosure under
15 the FOIA, 5 U.S.C. § 552 *et seq.*, and the Privacy Act, 5 U.S.C. § 552(a), *et seq.*

16 **THIRD AFFIRMATIVE DEFENSE**

17 3. The Court lacks jurisdiction over any matter to the extent Plaintiff failed to
18 satisfy prerequisites to suit, as well as over any requests or allegations that are not contained
19 in the FOIA request at issue in this action.

20 **FOURTH AFFIRMATIVE DEFENSE**

21 4. Plaintiff has not alleged sufficient factual and/or legal bases for its request
22 for costs and/or attorney's fees.

23 **FIFTH AFFIRMATIVE DEFENSE**

24 5. Plaintiff's request submitted under FOIA, 5 U.S.C. § 552, as amended, did
25 not reasonably describe the records sought.

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2. The Complaint be dismissed with prejudice;
3. No injunction relief be awarded to Plaintiff;
4. Defendant be awarded the costs of suit;
5. Judgment be entered in favor of Defendant;
6. The Court grant such other and further relief as it may deem proper.

Respectfully submitted this 10th day of August 2020.

MICHAEL BAILEY
United States Attorney
District of Arizona

s/Kristina L. Morrison
KRISTINA L. MORRISON
Assistant U.S. Attorney
Attorneys for Defendant NIH

1 **CERTIFICATE OF SERVICE**

2 I hereby certify that on August 10, 2020, I electronically transmitted the attached
3 document to the Clerk's Office using the CM/ECF System for filing and transmittal of a
4 Notice of Electronic Filing to the following CM/ECF registrant(s):

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s/ Irene Millsaps
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