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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

INFORMED CONSENT ACTION NETWORK, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, Defendant.	No. _____ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff, as for its Complaint against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. A novel coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 ("**COVID-19**") has resulted in federal government officials recommending numerous restrictions on everyday life in America. In response, all fifty states have implemented the recommended

restrictions to varying degrees, many of which press deeply upon cherished fundamental constitutional rights.

2. The National Institute of Allergy and Infectious Diseases ("**NIAID**") is at the center of the federal government's response to COVID-19. NIAID is an institute within the National Institutes of Health (**"Defendant"** or "**NIH**"). Dr. Anthony S. Fauci serves as NIAID's Director. Dr. Fauci has repeatedly asserted that "[f]inding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority."[1] To that end, NIAID has been funding and leading the development of mRNA-1273, the first vaccine for COVID-19 to enter into clinical trials.[2]

3. Plaintiff Informed Consent Action Network ("**Plaintiff**" or "**ICAN**") is a non-profit organization that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. Given its mission, ICAN and its founder, Del Bigtree, have received a litany of inquiries regarding COVID-19 and the vaccine being developed by NIAID for COVID-19.

4. In furtherance of its mission and in order to respond to the inquiries it has received, Plaintiff made a number of requests to NIH pursuant to the Freedom of Information Act (5 U.S.C. §552, as amended) ("**FOIA**") for documents regarding COVID-19 and a potential COVID-19 vaccine, including a request for "all safety and efficacy data and information regarding mRNA-1273, including from the Phase I clinical trial of this experimental vaccine." While NIH granted

[1] https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins (emphasis added).

[2] *See* https://www.clinicaltrials.gov/ct2/results?cond=COVID19&age_v=&gndr=&type=&rslt=&fund=0&Search=Apply.

expedited processing for this request, NIH has failed to further respond to this and all the other related requests submitted by ICAN as required under FOIA.

5. For all requests, NIH neither provided a determination letter as required by 5 U.S.C. § 552, nor produced any documents responsive to ICAN's FOIA requests. Each of the FOIA requests was proper and sought documents that NIH could have and should have easily been able to produce. ICAN therefore brings this action seeking an order directing Defendant to produce records responsive to ICAN's FOIA requests.

PARTIES

6. ICAN is a not-for-profit organization with offices in New York, Texas and Arizona, including at 2 North Central Avenue, Phoenix, AZ 85004.

7. Defendant National Institutes of Health is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. NIH is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

I. Background

9. The first vaccine for COVID-19 to begin trials in the United States is mRNA-1273.[3] This experimental vaccine is being developed by NIAID, the NIH institute directed by Dr. Fauci,

[3] *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

along with a biotechnology company, Moderna Inc.[4]

10. The first vaccine for COVID-19 to begin trials in the United States is mRNA-1273.[5] This experimental vaccine is being developed by NIAID, the NIH institute directed by Dr. Fauci, along with a biotechnology company, Moderna Inc.[6]

11. NIAID used taxpayer dollars to sponsor, assume responsibility for, and perform the first clinical trial for the mRNA-1273 vaccine.[7] Likewise, NIAID's parent department, the Department of Health and Human Services ("**HHS**"), awarded $483 million to accelerate development of mRNA-1273, including to "fund the development of mRNA-1273 to FDA licensure and manufacturing process scale-up to enable large-scale production in 2020 [before licensure is granted]."[8]

12. HHS has also granted those developing and those who will sell this product broad immunity from liability for injuries.[9]

13. Furthermore, a number of NIAID employees are listed as inventors on two patents relating to the development of mRNA-1273. [10] The first is patent application number 62/412,703 titled *Prefusion Coronavirus Spike Proteins and Their Use*[11] and the second is patent application

[4] *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[5] *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[6] *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[7] *See* https://clinicaltrials.gov/ct2/show/NCT04283461; https://projectreporter.nih.gov/project_info_history.cfm?aid=10110093&icde=49376321; https://projectreporter.nih.gov/project_info_description.cfm?aid=9872016&icde=49376321.

[8] https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19; https://investors.modernatx.com/node/8671/pdf.

[9] *See* https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

[10] *See* https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true (see "Competing interests" on page 4).

[11] *See* http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&f=G&l=50&d=PG01&S1=344,774&OS=344

number 62/972,886 titled *2019-nCoV Vaccine*.[12] NIAID employees listed on these patents include Barney Graham,[13] Masaru Kanekiyo,[14] Hadi Yassine,[15] Kizzmekia Corbett,[16] Michael Joyce,[17] and Olubukola Abiona.[18]

14. Because of the federal government's intimate involvement in developing mRNA-1273 and its support of this product, information regarding this potential COVID-19 vaccine is a matter of immediate concern to the American public. Indeed, news articles have widely reported about this vaccine.[19] Dr. Fauci has widely discussed this potential product in the media.[20] Moderna has similarly released press releases regarding this product, including announcing a secondary offering of $1,250,000,000 on the same day it released preliminary results from mRNA-1273's initial trial conducted by NIAID.[21]

,774&RS=344,774; https://www.ott.nih.gov/technology/e-234-2016.

12 *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

13 https://www.niaid.nih.gov/research/barney-graham-md-phd.

14 https://www.niaid.nih.gov/research/pathogenar-module-influenza-universal-vaccine.

15 *See* https://www.niaid.nih.gov/research/barney-graham-md-phd.

16 *See* https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0012686509.

17 *See* https://ned.nih.gov/search/ViewDetails.aspx?NIHID=0012508859.

18 *See* https://ned.nih.gov/search/ViewDetails.aspx?NIHID=2002358423.

19 *See* https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins; https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true; https://time.com/5835785/moderna-coronavirus-vaccine-phase-2/; https://www.businesswire.com/news/home/20200427005839/en/Moderna-Announces-IND-Submitted-U.S.-FDA-Phase; https://www.cnbc.com/2020/05/07/fda-approves-moderna-vaccine-candidate-for-phase-2-study.html; https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19; https://www.nytimes.com/2020/05/07/health/coronavirus-vaccine-moderna.html.

20 *See, e.g.*, https://www.cnn.com/2020/05/22/investing/moderna-coronavirus-vaccine-stock-sales/index.html ("Although the numbers were limited, it was quite good news because it reached and went over an important hurdle in the development of vaccines.").

21 *See* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine; https://investors.modernatx.com/static-files/49d9b447-214a-4f9d-802c-4b8cd4e3d269.

15. Judicial scholars have begun to opine regarding the legality of mandating this product to all adults. Alan Dershowitz, for example, recently stated that he would support such a mandate, adding that, "if you refuse to be vaccinated, the state has the power to literally take you to a doctor's office and plunge a needle into your arm."[22] Mr. Dershowitz appeared on ICAN's public broadcast, The HighWire with Del Bigtree, to defend this position, including specifically addressing mandating mRNA-1273 for adults.[23]

16. Moreover, states are expected to mandate the vaccine for all their residents. For example, the New York State Bar Association recently issued a report on COVID-19 recommending that, "[w]hen the efficacy of a COVID-19 vaccine has been confirmed" states should "enact legislation requiring vaccination of each person."[24]

17. Given the public interest in this product and the potential for states to mandate administering this product to nearly all their citizens, which is antithetical to informed consent, ICAN submitted a number of FOIA requests to NIH.

I. The FOIA Requests

18. On March 27, 2020, ICAN made the following requests to NIH related to mRNA-1273:

i. "Copies of any and all Employee Invention Report related to any vaccine or therapeutic for COVID-19." (**"FOIA Request 53821"**) (attached as Exhibit A)

ii. "Copies of any and all royalty or licensing agreements related to any vaccine or therapeutic for COVID-19." (**"FOIA Request 53822"**) (attached as Exhibit B)

iii. "A copy of the page of any patent application filed with regard to the mRNA-1273 vaccine which lists the inventors." (**"FOIA Request 53826"**) (attached as Exhibit C)

[22] https://youtu.be/tuoM3QGSUhM.
[23] *See* https://youtu.be/tuoM3QGSUhM.
[24] https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf.

19. On April 10, 2020, ICAN also made the following request to NIH: "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, subject, metadata, sender line, or recipient line of the email, or any attachment to the email." (**"FOIA Request 53963"**) (attached as Exhibit D). That same day, ICAN made this same request as to Barney Graham (**"FOIA Request 53962"**) (attached as Exhibit E), Kizzmekia Corbett, (**"FOIA Request 53961"**) (attached as Exhibit F), Michael Gordon Joyce (**"FOIA Request 53958"**) (attached as Exhibit G), Masaru Kanekiyo (**"FOIA Request 53960"**) (attached as Exhibit H), Olubukola Mary Abisola Abiona (**"FOIA Request 53959"**) (attached as Exhibit I), and Hadi Yassine (**"FOIA Request 54105"**) (attached as Exhibit J).

20. Thereafter, on May 5, 2020, ICAN made the following additional request to NIH: "All emails sent or received by Anthony Fauci between November 1, 2019 and the present that include the terms 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." (**"FOIA Request 54106"**) (attached as Exhibit K). That same day, ICAN made this same request as to Barney Graham (**"FOIA Request 54107"**) (attached as Exhibit L).

21. On May 22, 2020, ICAN submitted a FOIA request to NIH for: "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." (**"FOIA Request 54464"**) (attached as Exhibit M). Given the critical nature of this specific data, ICAN also requested that NIH grant expedited processing for this request.

22. NIH is required to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request

and shall immediately notify the person making such request of such determination and the reasons therefore." 5 U.S.C. § 552(a)(6)(A)(i). At a minimum, within 20 days of receiving each of ICAN's requests, NIH was required by 5 U.S.C. § 552(a)(6)(A)(i) to: (i) gather and review the requested records or seek a statutorily permitted extension; (ii) determine and communicate to ICAN the scope of any responsive records it intended to produce or withhold and the reasons for any withholdings; and (iii) inform ICAN that it had the right to appeal NIH's determination. *See, e.g.*, *Citizens for Responsibility and Ethics in Washington v. Federal Election Commission*, 711 F.3d 180, 188-89 (D.C. Cir. 2013).

23. Furthermore, if an agency grants expedited processing, it is obligated to process the request "as soon as practicable." 5 U.S.C. § 552(a)(6)(E)(iii).

II. NIH Fails to Properly Respond or Produce Any Documents

24. Despite the passage of more than 20 business days since NIH received each of the above requests, it has failed to provide a statutorily required response, including failing to: seek a permitted extension; determine and communicate to ICAN the scope of any responsive records it intended to produce or withhold and the reasons for any withholdings; or inform ICAN of its right to appeal.

25. Instead, for one request listed above (FOIA Request 53821), NIH merely sent ICAN a response stating that it is "In Process" (attached as Exhibit N). For another two listed requests (FOIA Requests 53822 and 53826), NIH only conveyed to ICAN that they had been "Received" (attached as Exhibit O). For six of the listed requests (FOIA Requests 53963, 53962, 53961, 53958, 53960 and 53959), NIH acknowledged the requests the day after they were filed, on April 10, 2020, as follows:

> This acknowledges your April 9, 2020 Freedom of Information Act (FOIA) request which was submitted to the National Institutes of

> Health (NIH) FOIA Office and received in that office the same day. Your request was referred to the National Institute of Allergy and Infectious Diseases (NIAID) FOIA Office because of our responsibilities under FOIA…We are searching the files of the Office of the Director, NIAID for records responsive to your request. If any documents responsive to your request are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner.

(attached as Exhibit P). For three other requests (FOIA Requests 54105, 54106 and 54107), the NIH, on May 5, 2020, only acknowledged receipt as follows:

> This acknowledges your April 29, 2020 Freedom of Information Act (FOIA) request addressed to Gorka Garcia-Malene, FOIA Officer, National Institutes of Health (NIH), which was received by the National Institute of Allergy and Infectious Diseases (NIAID) FOIA Office the same day…We are searching the files of the Vaccine Research Center, NIAID for records responsive to your request. If any documents responsive to your request are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner.

(attached as Exhibit Q).

26. On June 8, 2020, NIH recognized the "compelling need" to expeditiously release to the public the information requested by the May 22, 2020 FOIA Request 54464, writing to ICAN in relevant part as follows:

> In support of your request for expedited processing, you state that, "Information regarding this vaccine, and in particular the safety and efficacy information regarding this vaccine, are a matter of immediate concern to the American public." Your client's request meets the standards of "compelling need," therefore, I am granting your request for expedited processing.
>
> We are searching the files of the NIH for records responsive to your request. If any documents responsive to your request are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner.

(attached as Exhibit R).

27. After NIH's June 8, 2020 letter granting expedited processing, Plaintiff received no further communication or documents from NIH.

28. When an agency grants expedited processing, "a prima facie showing of agency delay exists when an agency fails to process an expedited FOIA request within the time limit applicable to standard FOIA requests." *Elec. Privacy Info. Ctr. v. Dep't of Justice*, 416 F. Supp. 2d 30, 39 (D.D.C. 2006). Therefore, because more than 20 business days have passed since filing FOIA Request 54464, NIH has presumptively failed to process FOIA Request 54464 in an expedited manner.

29. NIH has therefore failed to timely provide the responses required under FOIA for any of the FOIA Requests. NIH also failed to produce responsive documents and has not sought any of the statutorily available extensions of time available under FOIA. *ACLU of Wash. v. U.S. Dep't of Justice*, 2011 U.S. Dist. LEXIS 26047, at *32-33 (W.D. Wash. March 10, 2011) (finding the agency failed to act in a timely manner "[p]ursuant to FOIA § 552(a)(6)(C)" where "[defendant] did not seek an administrative extension of time in which to produce documents…[n]or did [defendant] respond to plaintiff's request for a fee waiver in a timely manner."). Nor did NIH provide a determination, and the reasons therefore, as to what records it intends to produce and the ones it intends to withhold. 5 U.S.C. § 552(a)(6)(A)(i)(I).

30. Furthermore, because NIH neither produced documents nor provided such a determination, NIH failed to provide ICAN with the required information to effectively submit an appeal as required by 5 U.S.C. § 552(a)(6)(A)(i)(II) and (III). *See, e.g.*, 5 U.S.C. § 552(a)(6)(C)(i); *Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 65 (D.C. Cir. 1990) ("A response is sufficient for purposes of requiring an administrative appeal if it includes: the agency's determination of whether

or not to comply with the request; the reasons for its decision; and notice of the right of the requester to appeal to the head of the agency if the initial agency decision is adverse."); (*Shermco Indus. v Sec'y of U.S. Air Force*, 452 F.Supp. 306, 318 (N.D. Tex. 1978), *rev'd on other grounds*, 613 F.2d 1314 (5th Cir. 1980)) (Plaintiffs were not required to exhaust their administrative remedies when defendant failed to provide plaintiffs with a complete determination because defendant's response "does not include a list of the releasable and withheld documents, does not include a statement of the fees charged for the releasable documents, and does not include a statement of why the agency believes waiver or reduction of any fee charged is not in the public interest or does not benefit the general public. The plaintiffs could not effectively appeal the [...] adverse decision on their FOIA request without this information.")

31. For these reasons, NIH has failed to abide by the requirements of FOIA and has forced ICAN to come before this Court to seek an order directing NIH to expeditiously produce all documents responsive to its FOIA requests. The information ICAN seeks is simply too important to the current public discourse regarding the COVID-19 pandemic to allow NIH to withhold such information from public scrutiny.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an Order directing NIH, within 10 days, to produce the requested documents;

c. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

d. Grant such other and further relief as the Court may deem just and proper.

Dated: June 29, 2020

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