Aaron Siri, AZ Bar No. 035890
SIRI & GLIMSTAD LLP
11201 North Tatum Boulevard, Suite 300
Phoenix, AZ 85028
Tel: (602) 806-9975
Fax: (646) 417-5967
aaron@sirillp.com

Elizabeth A. Brehm, *admitted pro hac vice*
SIRI & GLIMSTAD LLP
200 Park Avenue, Seventeenth Floor
New York, NY 10166
Tel: (212) 532-1091
Fax: (646) 417-5967
ebrehm@sirillp.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

INFORMED CONSENT ACTION NETWORK, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, Defendant.	No. CV-20-01277-PHX-JJT **PLAINTIFF'S OPPOSITION TO AND CROSS-MOTION FOR SUMMARY JUDGMENT AS TO REQUEST 54464**

Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") submits this Opposition to the National Institutes of Health's (**"Defendant"** or "**NIH**") Motion for Summary Judgment and its Cross-Motion for Summary Judgment. This opposition and cross-motion is supported by a Memorandum of Law and all matters of record.

MEMORANDUM OF LAW

I. Preliminary Statement

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

The National Institute of Allergy and Infectious Diseases ("**NIAID**"), an institute within the National Institutes of Health ("**NIH**"), is at the center of the federal government's response to COVID-19. NIAID has been funding and leading the development of mRNA-1273, the first vaccine for COVID-19 that entered into clinical trials.[1] (Pl. Statement of Facts ("**PSOF**") at ¶ 1.) On November 30, 2020, NIAID's corporate partner in developing the vaccine, Moderna, applied for FDA approval for the mRNA-1273 vaccine.

Informed Consent Action Network is a non-profit organization that advocates for informed consent and disseminates information necessary for same with regard to all medical interventions. In furtherance of its mission and in order to respond to the inquiries it has received, ICAN made a request to NIH pursuant to the Freedom of Information Act (5 U.S.C. §552, as amended) ("**FOIA**") for the request at issue: **"all safety and efficacy data and information regarding mRNA-1273, including from the Phase I clinical trial of this experimental vaccine."**

The NIH originally responded to ICAN stating that it had no efficacy data and that it was withholding in full the safety information pursuant to FOIA's exemption 4 (5 U.S.C. § 552(b)(4)) ("**Exemption 4**"). ICAN challenged both the adequacy of NIH's search and the withholding

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

pursuant to Exemption 4. Days before the original briefing was due in this action, NIH reversed course and informed ICAN that it would produce the previously withheld pages in full, subject to redactions pursuant to FOIA's Exemption 6 (5 U.S.C. § 552(b)(6)) ("**Exemption 6**"). NIH then produced one "Safety Summary Report" and its appendices on October 29 and November 9, 2020, respectively.

ICAN now challenges the adequacy of NIH's search and the appropriateness of a subset of the Exemption 6 redactions. Summary judgment is appropriate in favor of ICAN because NIH (i) inappropriately narrowed ICAN's request without its consent, and thereby conducted an inadequate search for responsive documents, and (ii) has improperly redacted information not protected by Exemption 6.

II. Factual Background

A. mRNA-1273 COVID-19 Vaccine

The first vaccine for COVID-19 to begin trials in the United States was mRNA-1273.[2] This experimental vaccine is being developed by NIAID, an NIH institute, along with a biotechnology company, Moderna Inc.[3]

NIAID used taxpayer dollars to sponsor, assume responsibility for, and perform the first clinical trial for the mRNA-1273 vaccine.[4] NIAID is the sponsor and collaborator and the named "Responsible Party" for the "Phase I, Open-Label, Dose-Ranging Study of the Safety and

---

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

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

[4] *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.

Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults ("Phase I").[5] There is an NIH Clinical Center location listed on NIH's clinicaltrials.gov website.[6] 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."[7] HHS has also granted those developing and those who will sell this product broad immunity from liability for injuries.[8] Furthermore, a number of NIAID employees are listed as inventors on two patents relating to the development of mRNA-1273.[9]

Because of the federal government's intimate involvement in developing mRNA-1273 and its support of this product, information regarding this potential vaccine is a matter of immediate concern to the American public. Indeed, news articles have widely reported about this vaccine.[10]

---

[5] *See* https://www.clinicaltrials.gov/ct2/show/NCT04283461.

[6] *Id*.

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

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

[9] *See* https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true (see "Competing interests" on page 4); *see also* 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=344,774&RS=344,774; https://www.ott.nih.gov/technology/e-234-2016; https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[10] *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.

Dr. Fauci has widely discussed this potential product in the media.[11] Moderna has similarly published press releases regarding this product, including preliminary results from mRNA-1273's initial trial conducted by NIAID.[12] (PSOF at ¶ 3.) And, on November 30, 2020, Moderna applied to the FDA for Emergency Use Authorization which, if granted, means the vaccine will soon be widely administered to Americans.[13] (PSOF at ¶ 4.)

Moreover, states are expected to mandate the vaccine for their residents. For example, the New York State Bar Association has already issued a report on COVID-19 recommending that, "a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required…"[14] (PSOF at ¶ 5.) Following that recommendation, on December 4, 2020, a bill was introduced in the New York Assembly allowing a mandate for all residents of the state.[15] (PSOF at ¶ 6.) Thus, it is reasonable to suspect that COVID-19 vaccines, including the Moderna vaccine, could become mandatory.

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 FOIA request to NIH regarding the vaccine's safety and efficacy.

---

[11] *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.").

[12] *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.

[13] *See* https://www.cnn.com/2020/11/30/health/moderna-vaccine-fda-eua-application/index.html; *see also* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-primary-efficacy-analysis-phase-3-cove-study. .

[14] https://nysba.org/app/uploads/2020/06/2b-REV-6-12-20-FINAL-HOD-RESOLUTIONS-1-through-4.pdf.

[15] *See* https://www.nysenate.gov/legislation/bills/2019/A11179?fbclid=IwAR3wfYN2BRGJm8goaNy_X188Mp-OxRu3qB9v0D-tckG3FPxryA6acLVWEKA.

B. The FOIA Request

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"**) (Dkt. No. 19-3.) Given the critical and time sensitive nature of this specific data, ICAN also requested that NIH grant expedited processing for this request.

In a June 8, 2020 letter to ICAN, NIH acknowledged that ICAN's "request meets the standard of 'compelling need'" and granted expedited processing. (Dkt. No. 19-4.) However, after this letter, ICAN received no further communication from NIH, forcing ICAN to come before this Court to seek an order directing NIH to expeditiously produce all documents responsive to its FOIA request.

C. NIH's Response

On August 13, 2020, ICAN received a letter from NIH responding to the request stating in relevant part: "The purpose of a Phase I trial is to establish safety. Thus, NIAID has access to the safety data, but no efficacy data. The safety data for this study comprises 1,093 pages. I have determined to withhold those records in their entirety pursuant to Exemptions 4 of the FOIA, 5 U.S.C. § 552 (b)(4), and sections 5.65 of the HHS FOIA Regulations, 45 CFR Part 5." (Dkt. No. 19-6.) Exemption 4 to FOIA is intended to protect "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[16]

On October 22, 2020, only eight days before NIH's summary judgment briefing was due to this Court, NIH reversed course and sent ICAN a letter stating: "the NIH has determined that it need not withhold this information any longer and anticipates producing the pages (with minor

[16] https://www.justice.gov/oip/foia-guide-2004-edition-exemption-4.

redactions pursuant to Exemption 6) on or before November 9, 2020." (Ex. A; PSOF at ¶ 7.) Exemption 6 permits the government to withhold information about individuals in "personnel and medical files and similar files" when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy."[17]

On October 29, 2020, NIH produced a 322-page "Safety Summary Report." Thereafter, on November 9, 2020, NIH produced 714 pages of Appendices to the "Safety Summary Report" report. The Appendices contained myriad redactions pursuant to FOIA Exemption 6 and there was no data produced regarding efficacy or immunogenicity.

In a November 12, 2020 letter to NIH, ICAN raised its objections that: (i) the documents produced are only partially responsive as to the request with regard to safety as the search was limited to "Phase I" clinical trial data; (ii) no responsive documents were searched for or produced with regard to efficacy; and (iii) there are extensive redactions in the "Safety Summary Report – Appendices" that ICAN challenges as improper. (PSOF at ¶ 8.)

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.

ARGUMENT

I. NIH's Search for Records was Inadequate

An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985). "The adequacy of the search is judged by a standard of reasonableness and depends upon the facts of each case. In considering the issue upon the agency's motion for summary judgment, the facts must be viewed in the light

[17] https://www.justice.gov/oip/foia-guide-2004-edition-exemption-6.

most favorable to the requester." *ACLU Found. of Ariz. v. United States Dep't of Homeland Sec.*, No. CV-14-02052-TUC-RM (BPV), 2017 U.S. Dist. LEXIS 11610, at *8 (D. Ariz. Jan. 26, 2017). NIH's Motion for Summary Judgment (Dkt. No. 18) and the accompanying FOIA Officer's Declaration (Dkt. No. 19) plainly establish that NIH has not met this burden.

As set out by NIH in its Motion for Summary Judgment, once the appropriate entity was identified, DMID, and after the correct individual at that entity was identified, Dr. Christopher Roberts, "the NIAID FOIA Office asked him to search his electronic files and emails for records related to the **safety data** for 'mRNA-1273' **and 'Phase 1**.'" (Dkt. No. 18 at 7, emphasis added; PSOF at ¶ 9.) First, this search was limited to safety data included in the Phase I portion of the clinical trials – a limit not included within ICAN's request. ICAN's request *included* data related to Phase I of the trials but did not in any way limit its request to that data. Second, this individual was not asked to search for any records related to the *efficacy* of the vaccine, which was clearly included in ICAN's request. Therefore, this search was not reasonably calculated to uncover all relevant documents. (PSOF at ¶¶ 10-11.)

A. ICAN's Request Was Not Limited to Phase I Data

ICAN's request is straightforward, it sought: "All safety and efficacy data and information regarding mRNA-1273[.]" ICAN then went on to provide examples of what it was looking for, stating in the request that it sought documents "including from the Phase I clinical trial of this experimental vaccine conducted by the National Institute of Allergy and Infectious Diseases." The phrase "including from" does not in any way limit the former part of the request for "[a]ll safety and efficacy data and information regarding mRNA-1273." (PSOF at ¶ 12.) NIH incorrectly characterizes ICAN's request as "specifically identif[ying] 'Phase I' as the subject of the request."

(*Id*. at 10; PSOF at ¶ 13.) The subject of the request is "all safety and efficacy data and information." It is not Phase I data.

Therefore, the search should not have been limited to only data and information related to the Phase I portion of the clinical trials. Instead, it should have covered all data and information in NIH's possession related to the safety and efficacy of the mRNA-1273 vaccine. ICAN is aware, from Moderna's press releases, that "[p]reclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available."[18] (Ex. B.) Any data and results from this trial regarding safety or efficacy (the obvious purpose of the study) would also be responsive to ICAN's request. However, NIH's briefing makes clear that it never conducted a search for any of these documents. (PSOF at ¶ 14.)

Because of NIH's incorrect interpretation, which had the effect of narrowing the request, any responsive documents that are not directly from "Phase I" would not have been discovered or produced.[19] Thus, the search conducted was inadequate.

B. ICAN's Request Included Data Regarding Efficacy

Even if NIH incorrectly interpreted ICAN's request to be limited to Phase I data (which it is not), the request plainly seeks data regarding mRNA-1273's efficacy. Contrary to NIH's claims,

---

[18] *See* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine.

[19] This is apparent from NIH's consistent and incorrect narrow description of ICAN's request throughout its Motion for Summary Judgment (e.g., "NIAID is the component that houses records related to 'mRNA-1273' and 'Phase I'" (Dkt. No. 18 at 7); "NIAID FOIA Office asked [Dr. Roberts] to search his electronic files and emails for records related to safety data for 'mRNA-1273' and 'Phase I'" (*id*.); "DMID and Dr. Roberts searched his files by using the following key words… 'Phase I'" (*id*.); "Although Plaintiff sought both safety and efficacy data of the Phase I trial…" (*id*. at 8); "Dr. Roberts was the DMID expert on Phase I…" (*id*. at 9); and generally).

Phase I of the clinical trials did include data on efficacy. Nevertheless, NIH neither searched for nor produced any data regarding efficacy. (PSOF at ¶ 15.)

ICAN does not challenge the June 2, 2020 cut-off date for the search. However, on May 18, 2020 – four days before ICAN's request was submitted and weeks before the June 2, 2020 cut-off date – NIAID's partner Moderna announced via press release "Positive Interim Phase I Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus." (Ex. B; PSOF at ¶ 16.) This press release, regarding Phase I of the clinical trial, discusses efficacy in terms of seroconversion, binding antibody levels, neutralizing antibody titers, immunogenicity data, and immune responses. The release also references a mouse challenge model and resulting protection against viral replication. All of these topics fall under the umbrella of efficacy. In fact, the first two statements and two of the first three paragraphs of the press release go to efficacy and not to safety. (PSOF at ¶ 17.)

These discussions in the press release regarding the interim data released by NIAID's partner directly contradict NIH's characterization of the "Phase I" portion of a clinical trial as focusing on safety. NIH, in explaining why no search was undertaken to identify efficacy data, represents that "Phase I did not assess efficacy" and that "Vaccine efficacy is therefore generally not addressed until Phase III of a clinical trial[.]" (Dkt. No. 18 at 8; PSOF at ¶ 18.) NIH then defined efficacy as "determin[ing] whether a vaccine can bring the intended beneficial effects on vaccinated individuals."

However, NIH's response rests on a broad assumption that because the Phase I trials focused on safety, they could not have produced any information regarding efficacy. Nothing in NIH's submissions supports this broad assumption. To the contrary, Moderna's press release regarding the Phase I trials expressly discusses the intended beneficial effects and the data

underlying the effects. Moderna's Chief Medical Officer stated: "These data substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease." (PSOF at ¶ 19.) This potential to prevent COVID-19 disease is precisely the intended beneficial effect on vaccinated individuals, defined by NIH as "efficacy." To be clear, Moderna's press release made plain in its first paragraph that this "positive interim clinical data of mRNA-1273" was "from the Phase 1 study *led by the National Institute of Allergy and Infectious Diseases (NIAID)*, part of the National Institutes of Health (NIH)." Thus, NIH led the Phase 1 study, it was aware of what data and documents were generated from that study, but NIH then failed to even conduct a search to locate responsive documents. (PSOF at ¶ 20.)

Moderna's reference to the efficacy of the vaccine in the press release indicates that the Phase I trials collected efficacy data, and that NIH knew about this. (PSOF at ¶ 21.) The fact that this data may have been collected required NIH to search for such data in response to ICAN's request. Moreover, Moderna's press release establishes that ICAN's claims about the existence and discoverability of other documents are not "purely speculative" as NIH now asserts. (Dkt. No. 18 at 6; PSOF at ¶ 22.)

As acknowledged by NIH, the "adequacy of a FOIA search is generally determined not by the fruits of the search, but by the appropriateness of the methods used to carry out the search." (Dkt. No. 18 at 6.) The methods employed by NIH inappropriately limited the search to Phase I clinical trial data and further limited that data to only safety data rendering its search inadequate. For these reasons, NIH has not met its burden under FOIA.

II. NIH Improperly Withheld Non-Private Information Which is Not Linked to Any Identifiable Individual Under FOIA Exemption 6

Under FOIA Exemption 6, an agency may withhold "medical files … the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C.

§ 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi Ag Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227, 380 U.S. App. D.C. 1 (D.C. Cir. 2008) (citation omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a *de minimis*, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875, 279 U.S. App. D.C. 27 (D.C. Cir. 1989).

ICAN does not have access to the names of the trial participants whose records are contained within the produced documents. Nor does ICAN challenge the redaction of the Subject IDs. (PSOF at ¶ 23.) Without access to these data (names and Subject IDs), ICAN has no way to discover the identities of any of the vaccine trial participants reflected in the produced documents. Removing any means of identifying the participants in the trial renders the remaining information protected – no one's personal privacy can be invaded or compromised if no one can be identified. As NIH has stated, Exemption 6 was "intended to cover detailed Government records on an individual *which can be identified as applying to that individual*." (Dkt. No. 11, emphasis added). However, because the identities of the trial participants are unknown, because their names are not included in the documents, and because even the Subject IDs are redacted within the documents (which ICAN does not challenge), the remaining information cannot be linked to any individual. Therefore, the disclosure of such information does not constitute an invasion of any significant privacy interest.

In *Yonemoto v. Dep't of Veterans Affairs*, the Ninth Circuit noted that even when "there are aspects of th[e] record that might cause 'embarrassment, shame, stigma, and harassment,'… disclosure would invade those privacy interests only if the information is linked to a particular, identifiable individual." *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 697 (9th Cir. 2012).

The information sought by ICAN is not personally identifying information and would not cause shame, stigma, or harassment. Nevertheless, even assuming, *arguendo*, the information sought might cause this, ICAN does not seek names, addresses, telephone numbers, email addresses, social security numbers, or any other information that would be linked to an individual person or reveal any person's identity. Instead, ICAN seeks the following information: adverse event experienced; alternative etiology of adverse event experienced; age of participant; comments regarding adverse events experienced; protocol deviations, reason for deviation, and deviation resolution; and a study site. (PSOF at ¶ 24.) This information is not tied to any individual, nor would it be even close to sufficient to "reverse engineer" the participant's identity. As such, this data does not implicate a personal privacy interest and so no privacy interest would be invaded if it were disclosed.

Under the Ninth Circuit's holding in *Yonemoto* an agency may redact personal information only where "disclosure implicates a personal privacy interest that is nontrivial, … or, put differently, [would be] more than *de minimis*." *Yonemoto*, 686 F.3d at 693. Here, any private information that could be released would be *de minimis*. The Supreme Court has held that even disclosure of "highly personal information" constitutes merely a *de minimis* invasion of privacy when the identities of the individuals are unknown and the invasion of privacy only "becomes significant when the personal information is linked to particular [individuals]." *United States Dep't of State v. Ray*, 502 U.S. 164, 175-176 (1991). As explained, the information sought by ICAN is not linked to any particular individuals whose identities are known. Therefore, it is a *de minimis* invasion, if any, and the agency should not be permitted to redact the requested data.

Furthermore, even if there was some risk that potentially private information would be released, which there is not, that risk would need to be weighed against "the public interest favoring

disclosure on the other." *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 693 (9th Cir. 2012). As NIH explained, the Court would examine whether "the public interest sought to be advanced is a significant one" and whether the "information sought is likely to advance that interest." (Dkt. No. 18 at 11).

The public's interest in the safety and efficacy of this COVID-19 vaccine could not be more significant. The entire country has been dramatically affected by COVID-19 and this vaccine (and other potential vaccines for this disease) have been lauded as the way we return to "normal." The myriad restrictions placed upon Americans that have affected their everyday lives – careers, educations, businesses, social interactions, leisure, mental health – hang in the balance and rest in large part on the successful administration of this vaccine to millions and millions of people. Facing potential mandates that all residents must receive the vaccine, the public must have full disclosure and transparency when it comes to both the safety and efficacy of this vaccine and the government's role in its development. Disclosure of the information sought by ICAN would serve to shed light on NIAID's and NIH's actions with regard to developing, purchasing, promoting, recommending, approving or licensing, and potentially mandating a COVID-19 vaccine.

In addition, the significant interest from the public cannot be outweighed by the almost non-existent risk that a trial participant's identification may be discovered after disclosure of the requested information, especially because at most the information the public would learn about would be trivial.

Additionally, the data sought sheds light on NIAID's activities. As acknowledged in NIH's Statement of Facts, NIAID "has sponsored" this vaccine trial "pursuant to a Clinical Trial Agreement between Moderna and NIAID. (Dkt. No. 19 at ¶¶ 4-5; PSOF at ¶ 25.) As explained in Section II, *supra*, NIAID has used taxpayer dollars to fund, sponsor, and run this trial and will

also be involved in the promotion and administration of this vaccine. Americans are entitled to understand the government's involvement in and results from such trials, especially when they are funding same.

The following are examples of the data that NIH redacted and discussions of why that data cannot qualify under Exemption 6.

"Adverse Events" – Appendix B to the "Safety Summary Report" is titled "Listing of Non-Serious, Unsolicited, Mild or Moderate, or Severe Adverse Events" and consists of 25 pages containing redactions applied by NIH under the column heading "Adverse Event." These adverse events are arguably the most critical portion of a Phase I clinical trial for the public to understand (i.e., what are the risks that the study found). (PSOF at ¶ 26.) The NIH itself acknowledged that this safety report was "designed to find possible vaccine safety issues, that is, an outcome or side effect that is believed to have resulted from administering a vaccine." (Dkt. No. 18 at 8.) Adverse events are how those outcomes and side effects are determined. The adverse events which are redacted are not, nor are they connected to, personal identifying information as explained above. These are simple descriptions of medical occurrences associated with the use of the experimental mRNA-1273 vaccine. (PSOF at ¶ 27.)

NIH represents that the adverse events are described within the "Safety Summary Report" itself. However, when presented in that fashion, one does not have access to the same information, including, for example, the number of days after vaccination when the adverse event occurred. (PSOF at ¶ 28.)

The disclosure of a description of an adverse event does not invade any unidentified person's privacy. Therefore, the redaction and withholding of this information is improper pursuant to Exemption 6.

"Alternative Etiology" – In the same appendix, Appendix B, the column entitled "If not related, alternative etiology" is also improperly redacted as it too could not reveal significant personal information. This column identifies the cause or origin (the etiology) of the adverse event when it is not related to the experimental vaccine. (PSOF at ¶ 29.) First, there are rows where the adverse event *has been found* to be related to the vaccine. NIH originally redacted this column approximately 40 times where it only read "N/A." (PSOF at ¶ 30.) This is troubling if it is any indication of the broad and improper use of exemptions. Second, for those instances where an adverse reaction has been found to not be related to vaccination, this column contains crucial information in order for one to verify whether or not there is an alternative, reasonable etiology for the adverse event. What that etiology is, again, is not tied to any personal identifying information. (PSOF at ¶ 31.) Therefore, again, there is no invasion of privacy which would result from its disclosure.

"**Age**" – Age, without any other identifying information, is not information the disclosure of which would invade or compromise personal privacy. NIH argues that this data "could be used to identify an actual patient[,]" but this is incredulous. Without having (or seeking) any trial participant names, Subject IDs, social security numbers, address, or other personally identifying information, age alone is not a risk for invasion of privacy. Knowing that a participant might, for example, be 23 years old, without other personally identifiable information, gets the public no closer to learning that person's identity, especially when there are likely millions of Americans who are age 23. Thus, age is not information "the release of which would cause a clearly unwarranted invasion of personal privacy." Therefore, these redactions are improper.

"**Comments**" – Appendices B, G1, and G2 contain "Comments" sections, all of which were redacted by NIH in its November 9, 2020 production. Evidencing NIH's general improper

and overuse of redactions is the fact that, 11 days after producing the redacted Appendices to ICAN, NIH re-produced another version of these Appendices unredacting *blank* "Comment" sections. NIH's counsel explained that: "many of the black boxes in the Comments section were applied when there was in fact no text in that space to redact." (Ex. C; PSOF at ¶ 32.)

If there is personal identifying information contained within the "Comments" sections which would allow the identity of the trial participant to become public (e.g., a participant's name, Subject ID, address), that particular information could be properly redacted pursuant to Exemption 6. However, the remaining information is not subject to Exemption 6.

"Deviations," "Reason for Deviation" and "Deviation Resolution" – Appendices G1 and G2 contain redactions in columns titled "Deviations," "Reasons for Deviation" and "Deviation Resolution." Appendix G1 is titled "Listing of Protocol Deviations." This appendix lists examples of deviations in trial protocol that took place, most of which are "too few aliquots obtained" or "required procedure done incorrectly." The reasons for these deviations, the resolutions, and the accompanying "comments" are all redacted. None of these columns appear to contain information that could be considered a patients' personal privacy information. (PSOF at ¶ 33.)

Appendix G2 is titled "Listing of Non-Subject Deviations" and the only deviation listed is redacted. This would appear to be a deviation that occurred not related to a trial subject and therefore, not protected by Exemption 6. (PSOF at ¶ 34.)

Again, if any personal identifying information is contained in these sections which would allow the identity of the trial participant to become public (e.g., a participant's name, Subject ID, address), that particular information could be properly redacted pursuant to Exemption 6. However, the remaining information is not subject to Exemption 6 as NIH has not shown that it is tied to any identified individual.

"Study Site" – Appendix G2 is titled "Listing of Non-Subject Deviations" and the NIH has improperly redacted information described above as well as "study site." NIH did not address this redaction in its papers nor did it include it in its Vaughn Index. (Dkt. No. 20-6.) However, it is clear that this appendix deals with "non-subjects", that identifying the study site is not "personal" information, and that no individual's privacy interest is invaded if that data is unredacted. (PSOF at ¶ 35.) Therefore, the application of Exemption 6 is improper.

For these reasons, because none of the categories of information sought will be "linked publicly with particular, named individuals" and any invasion of privacy would be insignificant, the NIH's application of Exemption 6 to that information was improper. *See Ray*, 502 U.S. at 175-176.

CONCLUSION

For the foregoing reasons, the Court should deny NIH's motion for summary judgment, grant Plaintiff's cross-motion for summary judgment, and order the NIH to disclose all responsive records.

Dated: December 11, 2020

/s/*Elizabeth A. Brehm*
AARON SIRI, AZ Bar No. 035890
SIRI & GLIMSTAD LLP
11201 North Tatum Boulevard, Suite 300
Phoenix, AZ 85028
Tel: (602) 806-9975
aaron@sirillp.com

ELIZABETH A. BREHM, *admitted pro hac vice*
SIRI & GLIMSTAD LLP
200 Park Avenue, 17th Floor
New York, NY 10166
Tel: (212) 532-1091
ebrehm@sirillp.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2020, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrant(s):

KRISTINA L. MORRISON
Assistant U.S. Attorney
Two Renaissance Square
40 N. Central Ave., Suite 1800
Phoenix, Arizona 85004
Telephone: 602-514-7500
kristina.morrison@usdoj.gov
Attorney for Defendant

/s/ Kimberly Hertz Stempien
SIRI & GLIMSTAD LLP