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 REPLY IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AS TO REQUEST 54464**

Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") submits this Reply in support of its Motion for Summary Judgement. This reply is supported by a Memorandum of Law and all matters of record.

MEMORANDUM OF LAW

I. Preliminary Statement

Plaintiff has met its burden for summary judgment because it demonstrated that Defendant did not conduct an adequate search in response to Plaintiff 's FOIA request and improperly applied redactions to the one report it did produce.

Plaintiff 's FOIA Request seeks:

> All safety and efficacy data and information regarding mRNA-1273 [the Moderna COVID-19 vaccine], including from the Phase I clinical trial of this experimental vaccine conducted by [NIAID].

Defendant continues to improperly narrow this request in two ways. First, Defendant's opposition pretends that Plaintiff 's request was only limited to seeking data regarding the Phase I clinical trial for the Moderna vaccine. It clearly was not. By its plain terms, Plaintiff 's request is seeking "[a]ll safety and efficacy data and information regarding [the Moderna vaccine]." The request merely used the Phase I trial clinical trial as an example of the information it was seeking. (*Infra* § I.A.)

The second way Defendant seek to improperly narrow Plaintiff's request is by defining "efficacy" to not include immunogenicity data. Defendant's position, however, is contrary to numerous peer reviewed publications, including those authored by NIH scientists, which refer to "efficacy" as "including immunogenicity". But even if Defendant's unreasonable interpretation of "efficacy" is accepted, Defendant ignores the fact that the request not only sought "safety and effect data" but also sought all "information" regarding the COVID-19 vaccine, which would include immunogenicity data. (*Infra* § I.B.)

After making these unilateral and improper limitations to the FOIA request, Defendant only searched the computer of a single individual to obtain records that referenced just "safety data" for the "Phase I" trial. The net result of this wholly inadequate search in response to a FOIA

request seeking all information regarding the Moderna vaccine was a single third-party report. It is incredible for Defendant to claim that this is the only responsive document to Plaintiff 's request since it literally co-developed the Moderna vaccine. For example, on March 16, 2020, Defendant proudly released a press release stating "[t]he vaccine is called mRNA-1273 and was developed by NIAID scientists and their collaborators at the biotechnology company Moderna. … Scientists at NIAID's Vaccine Research Center (VRC) and Moderna were able to quickly develop mRNA-1273 because of prior studies of related coronaviruses…"[1] The press release further states, with regard to the Phase I of this vaccine, a "protocol team will meet regularly to review safety data, and a safety monitoring committee will also periodically review trial data and advise NIAID." (*Infra* § I.B.)

In fact, there are two patents which relate to development of the Moderna vaccine on which individuals in NIAID are listed as inventors.[2] The first is patent application number 62/412,703 entitled *Prefusion Coronavirus Spike Proteins and Their Use* and the second is patent application number 62/972,886 entitled *2019-nCoV Vaccine*.[3] The following are the individuals in NIAID that are listed as inventors on one or both of these patents and each of them and their heirs stand to personally earn millions of dollars from the sale of this product in the coming years:[4]

Barney Graham, Deputy Director, NIAID Vaccine Research Center
Kizzmekia Shanta Corbett, Scientific Lead, NIAID's Coronavirus Vaccine Program
Michael Gordon Joyce, NIAID
Hadi Yassine, NIAID
Masaru Kanekiyo, NIAID
Olubukola Abiona, NIAID

[1] https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins
[2] https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?versioned=true
[3] *Id.*; https://www.ott.nih.gov/technology/e-234-2016;
[4] https://www.ott.nih.gov/royalty/information-nih-inventors

Thus, there is no question that Defendant played in integral role in the vaccine's creation, and it is disingenuous for Defendant to imply otherwise. In the face of its extensive involvement, Defendant asks this Court to believe that the only "safety and efficacy data" and, in fact, the only "information" in its possession regarding this vaccine, is a single report produced by a third-party. This position strains credulity and is an affront to the obvious. (*Infra* § I.B.)

Additionally, as for the one document it produced, NIH improperly redacted anonymized data that cannot possibly be linked to any identified individual. (*Infra* § II.)

ARGUMENT

I. NIH's Search was Inadequate and Unreasonable

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) (emphasis added). "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 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).

Furthermore, this Court has explained "the underlying facts and possible inferences are construed in favor of the FOIA requester" because "the party seeking disclosure does not know the contents of the information sought and is, therefore, helpless to contradict the government's description of the information or effectively assist the trial judge." *ACLU of Ariz. v. United States Dep't of Homeland Sec. Office*, No. CV-15-00247-PHX-JJT, 2017 U.S. Dist. LEXIS 128518, at *5-6 (D. Ariz. Aug. 14, 2017) (internal citations omitted). This issue is compounded by the fact that "[o]rdinary rules of discovery, in which each party has access to the evidence upon which the

court will rely in resolving the dispute, do not apply. Instead, one party maintains sole access to the complete universe of facts and documents." *Wiener v. FBI*, 943 F.2d 972, 977 (9th Cir. 1991). It is therefore inappropriate for Defendant to "deem admitted" any statements made by Defendant about which Plaintiff would have no personal knowledge and to characterize this complete imbalance as "evidentiary deficiencies."

A. Plaintiff's Request Was Not Limited to Data from the Phase I Trial

Plaintiff's request is straightforward. It sought: "All safety and efficacy data **and information** regarding mRNA-1273[.]" (Dkt. No. 1 at 51) (emphasis added.) Contrary to Defendant's repeated contention in its opposition papers, Plaintiff's request was not limited to Phase I clinical trial data but encompassed all information regarding the Moderna vaccine. While the Court is not tasked with determining if the documents requested actually exist, it is tasked with determining if the agency conducted a sufficient search. *Perry v. Block*, 684 F.2d 121, 128, 221 U.S. App. D.C. 347 (D.C. Cir. 1982).

Here, Defendant's search was categorically inadequate. Defendant's declaration supporting the adequacy of its search makes plain that it limited it search to information regarding the "clinical trial" for the Moderna vaccine. Indeed, the FOIA request was first sent by Defendant to NIAID's Vaccine Research Center (VRC), where the Moderna vaccine was developed, which without any doubt has "information" related to this vaccine. But instead of obtaining the responsive records to the FOIA request that the VRC possesses, the VRC was given a pass on producing anything because, as explained by Defendant, the "VRC responded that it did not have any responsive records because it is neither the sponsor of the [Phase I] clinical trial for the experimental vaccine **'mRNA-1273'** nor the holder or owner of any of the [Phase I] data that

Plaintiff requested." (Dkt. No. 19-2 at ¶ 16) (emphasis in original.) But the FOIA request on its face is not limited to the Phase I clinical trial data.

Defendant should be enjoined to have the VRC to produce all "information" related to the Moderna vaccine. The head of the VRC and employees within the VRC are literally holders of the very patents used to develop the Moderna vaccine. This vaccine was developed in the VRC. But yet Defendant is seriously claiming the VRC has no "information" regarding a vaccine it developed, patented, tested, conducted lab experiments for, and, as widely publicized, has created.

B. Defendant Further Improperly Limited Plaintiff's Request to "Safety" from the Phase I Clinical Trial

Having improperly limited Plaintiff's request to clinical trial data – and having given the VRC a pass on producing any responsive documents – Defendant then sent the request to NIAID's Division of Microbiology and Infectious Diseases ("DMID") **where the work computer of a single individual, Dr. Christopher Roberts for "safety data for 'mRNA-1273' and 'Phase I.'"** (Dkt. No. 19-2 at ¶ 17.) Limiting Plaintiff's request to only "Phase I" data alone was improper. Defendant now added another improper limitation: limiting the search to only "safety data" in the Phase I trial. And, further, Defendant then incredibly only searched a single individual's computer.

Defendant's unilateral decision to limit Plaintiff's request to only "safety data" (and only for the Phase I trial) was entirely improper. The FOIA request also sought all "efficacy data" and also sought all "information" regarding the Moderna vaccine. Defendant simply ignores the fact that the request sought all "information" in its opposition and argues that the term "efficacy" can be ignored since the Phase I trial only gathers immunogenicity data and not efficacy data. Putting aside that the FOIA request asked for all "information" (which would include immunogenicity data) and was not limited to Phase I data, the term "efficacy" can certainly include immunogenicity.

Indeed, scientists, including NIH scientists, in peer reviewed publications, have repeatedly written "efficacy, including immunogenicity," hence explicitly including immunogenicity as part of efficacy. *See, e.g.,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6452401/ ("efficacy, including immunogenicity"); https://pubmed.ncbi.nlm.nih.gov/10508704/ ("efficacy, including immunogenicity"); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3604642/ ("efficacy, including immunogenicity"); https://link.springer.com/article/10.1007%2Fs10067-019-04496-3 ("efficacy, including immunogenicity"). But even if this were not so, the request is not limited to "efficacy" but includes all "information" which certainly would encompass "immunogenicity."

The FOIA request expressly seeks all "safety and efficacy data" and all "information" regarding the Moderna vaccine. No objection to the scope of this request was ever made by Defendant. Instead, Defendant has chosen to unilaterally and improperly limit its scope to only safety data from the Phase I trial of the Moderna vaccine and then to only search a single individual's computer for its self-made scope which resulted in the single report produced.

Defendant should be enjoined to produce all "information," meaning all documents it has with regard to the Moderna vaccine, including those of the individuals within VRC and certainly the individuals at the VRC that worked on developing this vaccine and those at Defendant that hold patents on this vaccine. It should not be permitted to improperly limit its search to a single individual's' "electronic files and emails for records related to safety data for 'mRNA-1273' and 'Phase I,' which would be responsive to Request 54464." (Dkt. No. 19-2 at ¶ 17.) *See Rollins v. U.S. Dep't of State*, 70 F.Supp.3d 546, 550 (D.D.C. 2014) (the agency cannot ignore "*clear leads* ... [that] may indicate ... other offices that should have been searched."); *see also Weisberg v. U.S. Dep't of* Justice, 705 F.2d 1344, 1351 (D.C. Cir. 1983) ("What the agency must show beyond material doubt is that it has conducted a search reasonably calculated to uncover all relevant

documents···The adequacy of an agency's search is measured by a standard of reasonableness and is dependent upon the circumstances of the case") (internal citations omitted).

II. NIH's Redactions Are Improper and Unjustified as No Privacy Interest is Implicated

In the single document produced, Defendant has improperly redacted information that does not implicate a privacy interest. Plaintiff is not seeking, nor does it have access to, any individual's name, address, social security number, Subject I.D., or any other personally identifying information. Plaintiff agrees that these categories of data would be exempt from disclosure.

The redactions that Plaintiff challenges are not exempt as they would not reveal information that would make it possible to identify any specific individual. As FOIA demands, "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under [§ (b)]." 5 U. S. C. § 552(b).

Plaintiff challenges redactions in the following categories of the produced report: "Adverse Event," "If Not Related, Alternative Etiology," "Age," "Comments," "Reasons for Deviation," and "Deviation Resolution." (Dkt. Nos. 19-7 through 20-4.) None of these categories contains information which would allow Plaintiff to identify a specific individual. All patient data is anonymized and since Plaintiff has no access to list of individuals, any other personally identifying information, or Subject IDs, this information is not able to be tied to any identifiable person. Therefore, there is no privacy interest at stake.

Defendant attempts to confuse the issue by roping in the HIPAA Privacy Rule as a justification for the redactions. However, this rule, codified at 45 C.F.R. § 164.514, protects individually identifiable health information. The rule enumerates the following list of identifiers that once removed render medical records not individually identifiable: names; geographic subdivisions smaller than a state (including addresses and full zip codes); all dates directly related

to an individual except years; telephone and fax numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; license numbers; vehicle identifiers; device identifiers; internet addresses; biometric identifiers such as finger and voice prints; photographs of an individual's full face; and any other unique identifying number, characteristic, or code. *See* § 164.514(b)(2)(i).

As explained by another federal court, "**Records without this data are not considered to be individually identifiable, and therefore are not protected health information**. Accordingly, by redacting such data from [the reports], the reports will no longer contain protected health information and can be produced in discovery, even without a protective order." *Rice v. Union Cent. Life Ins. Co.*, No. CV 05-216-S-BLW, 2006 U.S. Dist. LEXIS 27248, at *18-19 (D. Idaho Apr. 26, 2006) (emphasis added).

Notably, Defendant does not address the Supreme Court's holding 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) (emphasis added). Here, the information being sought is neither highly personal (e.g., age, reason for deviation) nor is the universe of individuals known and so, certainly, the information is not linked to any particular person. Therefore, if any invasion, it is an insignificant and *de minimis* one and does not satisfy that the interests at stake constitute a nontrivial privacy interest.

Instead, Defendant cites *Cameranesi v. U.S. Dep't of Def.* to argue that it need only show the privacy interests as stake "constitute 'some nontrivial privacy interest in nondisclosure.'" (Dkt. No. 26 at 10.) *Cameranesi* is inapposite. There, potential disclosure of individuals' names was at

issue and the court had to address the question of whether such disclosure "would subject [them] to possible embarrassment and retaliatory action." This is not the case here. Plaintiff is not seeking any names of individuals; the redactions being challenged are segregated from any identifying information.

Likewise, *Painting Indus. Of Haw. Mkt. Recovery Fund*, cited by Defendant, deals with a request that includes the disclosure of names and addresses. That court held that although some of the requested information was otherwise publicly available in one form, the requester was not entitled to additional information because the individuals at issue "have a substantial privacy interest in information **tying their names and addresses to** precise payroll figures." *Painting Indus. Of Haw. Mkt. Recovery Fund v. U.S. Dep't of the Air Force*, 26 F.3d 1479, 1484 (9th Cir. 1994) (emphasis added). Again, the data sought by Plaintiff would not tie any individuals to medical data and so no substantial privacy interest exists.

Defendant does not and cannot refute *Yonemoto v. Dep't of Veterans Affairs*, wherein 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). Instead, Defendant offers an example of a redaction demonstrating the complete lack of a link to any particular, identifiable individual: "for a participant reporting an [adverse] event of 'throbbing pain inside my head behind my eye,' that phrase is captured in the database but was redacted…" (Dkt. No 26 at 11.) There is nothing within the phrase "throbbing pain inside my head behind my eye" that links this information with any identifiable person. Coding this phrase as "headache" does nothing to further

de-identify or anonymize the data. Defendant's redactions protect nothing and merely withhold additional, non-protected information from the public.

It is simply not possible to identify a specific individual based on an adverse event descriptions ("throbbing pain inside my head"), age, and/or reason for protocol deviation given that other identifying information is unavailable. *See 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 *70 (D. Ariz. Jan. 26, 2017) (ordering disclosure where "the impracticality of determining the identity of persons from reference to [the redacted information]" is attenuated, "especially in light of the fact that other identifying information will remain redacted"). Consequently, Defendant's redactions are improper as Exemption 6, as stated by Defendant, was "intended to cover detailed Government records on an individual *which can be identified as applying to that individual*." (Dkt. No. 11, emphasis added).

The government has not identified a cognizable privacy interest. Therefore, there is no need to balance disclosure of private data against public interest. *See Our Children's Earth Found. v. Nat'l Marine Fisheries Serv.*, 85 F. Supp. 3d 1074, 1085 (N.D. Cal. 2015) ("First, the Court must determine if disclosure implicates a personal privacy interest that is nontrivial. If the agency fails to establish that disclosure would lead to the invasion of a non-trivial personal privacy interest protected by Exemption 6, the FOIA demands disclosure, without regard to any showing of public interest.") (internal citations omitted); *see also Lahr v. NTSB*, 569 F.3d 964, 974 (9th Cir. 2008) and *Cameranesi v. United States DOD*, 856 F.3d 626, 637 (9th Cir. 2017).

In any event, the data being sought sheds light on NIH's activities and advances a public interest. Simply because NIH "did not provide direct care and treatment" at this stage of the clinical trial does not mean the data sheds no light on its workings. As acknowledged in NIH's

Statement of Facts, and widely publicized by NIH and other public health agencies, NIAID "co-developed"[5] this vaccine and "has sponsored" its clinical trial "pursuant to a Clinical Trial Agreement between Moderna and NIAID." (Dkt. No. 19 at 4-5.) The agency used taxpayer dollars for these efforts. This trial and its data and outcomes are a result of NIAID's sponsorship, work, agreements with Moderna, and activities.

CONCLUSION

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

Dated: January 29, 2020

/s/ Elizabeth Brehm
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

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

Attorneys for Plaintiff

[5] *See* https://www.niaid.nih.gov/news-events/statement-nih-and-barda-fda-emergency-use-authorization-moderna-covid-19-vaccine and https://www.nih.gov/news-events/news-releases/experimental-covid-19-vaccine-safe-generates-immune-response.