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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Informed Consent Action Network, Plaintiff, v. National Institutes of Health, Defendant.	No. CV-20-01277-PHX-JJT **ORDER**

At issue is Defendant National Institutes of Health's ("NIH") Motion for Summary Judgment (Doc. 18, "NIH MSJ"), to which Plaintiff Informed Consent Action Network ("ICAN") filed a Response and Cross-Motion for Summary Judgment (Doc. 21, "ICAN CMSJ & Resp."). NIH subsequently filed a Response to ICAN's Cross-Motion for Summary Judgment and Reply in support of its Motion for Summary Judgment (Doc. 26, "NIH Resp. & Reply"), and ICAN filed a Reply (Doc. 28, "ICAN Reply"). The Court also considered ICAN's Letter to the Court (Doc. 29, "ICAN Letter") as well as NIH's Response to ICAN's Letter to the Court (Doc. 30, "NIH Resp. to Letter") and NIH's Supplemental Response to ICAN's Letter to the Court (Doc. 32, "NIH Suppl. Resp. to Letter"). The Court finds these matters appropriate for resolution without oral argument. *See* LRCiv 7.2(f). For the reasons that follow, the Court will grant in part and deny in part both NIH's Motion for Summary Judgment as well as ICAN's Cross-Motion for Summary Judgment.

I. BACKGROUND

The following facts are undisputed unless otherwise noted. This case arises out of ICAN's Freedom of Information Act ("FOIA") Requests to NIH and NIH's subsequent responses regarding the mRNA-1273 vaccine (the "Vaccine") to combat SARS-COV-2 Infection ("COVID-19"). The NIH is the United States's medical research agency. It has multiple components, including The National Institute of Allergy and Infectious Diseases ("NIAID"). (Doc. 19, NIH's Statement of Facts ("NSOF" ¶¶ 1-2.)) The NIAID funded and led the development of the vaccine. (Doc. 23, ICAN's Separate Statement of Facts in Support of its Cross-Motion for Summary Judgment ("ISSOF") ¶ 1.) Moderna TX, Inc. ("Moderna") is a private biotechnology company that manufactured the vaccine and brought it to market. (NSOF ¶ 3.) NIAID sponsored Phase I of the Vaccine's clinical trial. The trial evaluated the safety of the vaccine as well as its ability to induce an immune response in the Phase I study participants ("patients") (NSOF ¶ 6.) Phase I started on March 16, 2020 and had 85 patients enrolled as of May 25, 2020. (NSOF ¶ 8.)

On May 22, 2020, ICAN sent Request 54464 (the "Request") to NIH, which NIH then forwarded to NIAID. (NSOF ¶ 11; Doc. 19-3, Attach. A.) The Request sought:

> 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.

NIAID sent the Request to one of its components, the Vaccine Research Center ("VRC"). The VRC advised that it did not have any responsive information because it did not sponsor the Phase I trial but suggested sending the Request to the NIAID's Division of Microbiology and Infectious Diseases ("DMID"), which helped conduct Phase I. (NSOF ¶ 13.) On June 2, 2020, NIAID FOIA staff sent the Request to Dr. Christopher Roberts, the official in charge of the DMID vaccine program, and requested that he search for records related to safety data for "mRNA-1273" and "Phase I." (NSOF ¶¶14-15.)

DMID used the cut-off date of June 2, 2020 for its search. (DSOF ¶ 17.) ICAN does not dispute that this was the correct date. (Doc. 22, ICAN's Controverting Statement of

Facts ("ICSOF") ¶ 17.) At this time, NIH did not possess data or records regarding subsequent clinical trial phases. (NSOF ¶ 25.) DMID searched the electronic database using the keywords "mRNA-1273," "Phase I," "Moderna," "DMID 20-003," and "safety data reports." (NSOF ¶ 18.). The search did not include the term "efficacy." (ISSOF ¶ 11.)

The search returned one document, a 1,093-page Safety Summary Report (the "Safety Report"). NIH informed Moderna of the search's results and Moderna requested that NIH withhold the Safety Report in its entirety pursuant to Exemption 4. (NSOF ¶ 31.) On August 13, 2020, NIH informed ICAN that because the "purpose of a Phase I trial is to establish safety… NIAID has access to safety data, but no efficacy data," and that it had withheld the Safety Report. (NSOF ¶ 32.) After Moderna informed NIH that it could release the Safety Report with certain portions redacted, NIH redacted portions of the patients' information. (NSOF ¶ 33.) NIH produced a redacted version of the Safety Report to ICAN on October 29, 2020. (NSOF ¶ 34.) Subsequently, on November 20, 2020, NIH provided ICAN a version of the Safety Report with reduced redactions. (NSOF ¶ 35.)

Specifically, pursuant to Exemption 6, NIH redacted the following data and information: 1) the patients' Subject IDs, 2) Adverse Event, 3) If Not Related, Alternative Etiology, 4) Age, 5) Comments, and 6) Reasons for Deviation and Deviation Resolution. (NSOF ¶¶ 37-64.)

The parties now both move for summary judgment on the adequacy of NIH's search and subsequent production as well as whether the redactions are proper under Exemption 6.

II. LEGAL BACKGROUND

A. FOIA

Congress enacted FOIA to "facilitate public access to Government documents." *DOS v. Ray*, 502 U.S. 164, 173 (1991). Accordingly, FOIA "mandates a policy of broad disclosure of governmental documents." *Maricopa Audubon Soc'y. v. Forest Serv.*, 108 F.3d 1082, 1085 (9th Cir. 1997) (quotation and citation omitted). FOIA "seeks to permit access to official information long shielded unnecessarily from public view and attempts to create a judicially enforceable public right to secure such information from possibly

unwilling official hands." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 151-52 (1989) (citation omitted).

When a request is made, a governmental agency may withhold all or portions of a document "only if material at issue falls within one of the nine statutory exemptions found in § 552(b)." *Maricopa Audubon Soc'y*, 108 F.3d at 1085. The exemptions are "explicitly exclusive." *DOJ v. Tax Analysts*, 492 U.S. 136 (1989). Moreover, they must be "narrowly construed in light of FOIA's dominant objective of disclosure, not secrecy." *Maricopa Audobon Soc'y*, 108 F.3d at 1085 (quotation and citation omitted).

As courts have noted, "the district court's review in a FOIA case is difficult 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." *Hronek v. DEA*, 16 F. Supp. 2d 1260 (D. Oregon 1998) (quoting *Davin v. DOJ*, 60 F.3d 1043, 1049 (3d. Cir. 1995).) Ordinary 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). Thus, "the underlying facts and possible inferences are construed in favor of the FOIA requester." *L.A Times Commc'ns, LLC v. Dep't of Army*, 442 F. Supp. 2d 880, 894 (C.D. Cal. 2006) (citations omitted).

The district court is required to conduct a *de novo* review of the government agency's decision to withhold requested information. 5 U.S.C. § 522(a)(4)(B). The burden to justify the refusal to turn over responsive documents rests with the government. *Bloomberg, L.P. v. Bd. of Governors of the Fed. Reserve Sys.*, 601 F. 3d 143, 147 (2d Cir. 2010).

B. Summary Judgment

"Summary judgment is the procedural vehicle by which nearly all FOIA cases are resolved." *Nat'l Res. Def. Council v. DOD*, 388 F. Supp. 2d 1086, 1094 (C.D. Cal. 2005) (quotations omitted). Because the facts are rarely in dispute in a FOIA case, the Court need

not ask whether there is a genuine issue of material fact. *Minier v. CIA*, 88 F.3d 796, 800 (9th Cir. 1996); *but see Torres Consulting & Law Grp., LLC v. NASA*, 666 F. App'x 643, 644 (9th Cir. 2016) ("[I]f there are genuine issues of material fact in a FOIA case, the district court should proceed to a bench trial or adversary hearing. Resolution of factual disputes should be through the usual crucible of bench trial or hearing, with evidence subject to scrutiny and witnesses subject to cross-examination.").

The standard for summary judgment in a FOIA case generally requires a two-stage inquiry. *L.A Times Commc'ns, LLC*, 442 F. Supp. 2d at 893. Under the first step of the inquiry, the Court must determine whether the agency has met its burden of proving that it fully discharged its obligations under FOIA. *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985). In the second stage, the Court examines whether the agency has proven that the information that it withheld falls within one of the nine FOIA exemptions. 5 U.S.C. § 552(a)(4)(B); *DOS v. Ray*, 502 U.S. 164, 173 (1991) ("The burden remains with the agency when it seeks to justify the redaction of identifying information in a particular document as well as when it seeks to withhold an entire document."); *Dobronski v. FCC*, 17 F.3d 275, 277 (9th Cir. 1994).

The government may submit affidavits to satisfy its burden, but "the government may not rely upon conclusory and generalized allegations of exemptions." *Kamman v. IRS*, 56 F.3d 46, 48 (9th Cir. 1995) (quotation and citation omitted). The government's "affidavits must contain 'reasonably detailed descriptions of the documents and allege facts sufficient to establish an exemption.'" *Id.* (internal citation omitted). To carry their burden on summary judgment, "agencies are typically required to submit an index and 'detailed public affidavits' that, together, 'identify[ ] the documents withheld, the FOIA exemptions claimed, and a particularized explanation of why each document falls within the claimed exemption.'" *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 688 (9th Cir. 2012), *overruled on other grounds by Animal Legal Def. Fund v. DEA*, 836 F.3d 987 (9th Cir. 2016) (quoting *Lion Raisins v. Dep't of Agric.*, 354 F.3d 1072, 1082 (9th Cir. 2004) (same)). These submissions—commonly referred to as a *Vaughn* index — must be from

"affiants [who] are knowledgeable about the information sought" and "detailed enough to allow courts to make an independent assessment of the government's claim [of exemption]." *Id.* (citing *Lion Raisins*, 354 F.3d at 1079; 5 U.S.C. § 552(a)(4)(B)). Courts "accord substantial weight to an agency's declarations regarding the application of a FOIA exemption." *Shannahan v. IRS*, 672 F.3d 1142, 1148 (9th Cir. 2012) (citation omitted).

In short, Defendants must show that "its search for responsive records was adequate, . . . any exemptions claimed actually apply, . . . [and] any reasonably segregable non-exempt parts of records have been disclosed after redaction of exempt information." *Light v. DOJ*, 968 F. Supp. 2d 11, 23 (D.D.C. 2013).

III. ANALYSIS

A. Adequacy of the Search

NIH moves for summary judgment on the grounds that it conducted a reasonable search for responsive records. (NIH MSJ at 6-10; NIH Resp. & Reply at 3-7.) ICAN responds and similarly moves, arguing that Defendant has failed to demonstrate search adequacy, both in employing overly narrow search terms, and failing to search relevant repositories. (ICAN CMSJ & Resp. at 7-11; ICAN Reply at 4-8.)

To comply with FOIA, an agency must conduct a "search reasonably calculated to uncover all relevant documents." *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985) (quotation and citation omitted). At summary judgment, an agency must demonstrate "'beyond material doubt . . . that it has conducted" such a search. *S. Yuba River Citizens League v. Nat'l Marine Fisheries Serv.*, 2008 WL 2523819, at *11 (E.D. Cal. June 20, 2008) (quoting *Zemansky*, 767 F.2d at 571). The agency is not required to search every record system, but may limit itself to those systems in which it believes responsive records are likely to be located. *Amnesty Int'l USA v. CIA*, 728 F. Supp. 2d 479, 497 (S.D.N.Y. 2010). FOIA requires only "a reasonable search for records, not a perfect one." *Hamdan v. DOJ*, 797 F.3d 759 at 772 (9th Cir. 2015). In conducting its search, the agency may rely on "reasonably detailed, non-conclusory affidavits and declarations submitted in good faith." *Id.* Those affidavits must describe "what records were searched, by whom, and

through what process." *Lawyers' Comm. for Civil Rights v. U.S. Dep't of the Treasury*, 534 F. Supp. 2d 1126, 1131 (N.D. Cal. 2008) (citation omitted). These requirements are "to afford a FOIA requester an opportunity to challenge the adequacy of the search and to allow the district court to determine if the search was adequate in order to grant summary judgment." *Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 68 (D.C. Cir. 1990). The court is tasked with determining if the agency conducted a sufficient search for the documents requested, not determining if the documents requested actually exist. *Perry v. Block*, 684 F.2d 121, 128 (D.C. Cir. 1982).

1. Search Terms

ICAN contends that NIH improperly narrowed the search by using the term "Phase I" because the Request asked for all data and information related to the safety and efficacy of the Vaccine rather than just Phase I data and information. (ICAN CMSJ & Resp. at 8-9.) The Court agrees that ICAN did not limit the Request to Phase I but fails to see how NIH's inclusion of the term improperly limited the search. NIH avers, and ICAN does not contest, that at the time of the search, NIH did not possess data on subsequent trial phases. (NSOF ¶ 25; ISCSOF ¶ 25.) Moreover, NIH's search included broader terms such as "mRNA-1273" that would likely capture responsive documents not in Phase I. Indeed, ICAN does not offer other search terms that NIH should have used to broaden the search.[1] And with the exception of the results from the preclinical viral challenge study in mice, discussed *infra*, ICAN does not contend that ICAN withheld specific documents because they were not part of Phase I. Therefore, ICAN failed to produce evidence to support its contention that the search term "Phase I" unduly restricted NIH's search and production of responsive documents.

Likewise, ICAN argues that NIH erred by neither searching for nor producing documents regarding "efficacy." (ICAN CMSJ & Resp. at 9-11.) NIH contends that it did it did not study the efficacy of the Vaccine until Phase III of the clinical trial, which did

[1] ICAN does argue that NIH should have included the search term "efficacy," which the Court addresses *infra*. However, this is a separate issue from ICAN's contention that using "Phase I" as a search term improperly narrowed the search.

not start until July 27, 2020 and thus NIH could not search for or produce such documents. (NIH MSJ at 8-9.) NIH produces evidence explaining how to test for efficacy and details how and why the Phase I trial did not assess efficacy. Specifically, Dr. Roberts explains:

> Phase I trial does not evaluate the efficacy of the vaccine. Vaccine efficacy data shows the extent to which a vaccine can protect against an infection or disease. Efficacy studies are done by giving one group of people a vaccine and comparing the incidence of disease in that group to that of another group of people who do not receive the vaccine. If there is more disease in one group than the other, there are efficacy analyses that can be performed to determine if this occurred by chance or was because the vaccine protected against the infection (or symptoms, or hospitalizations, etc. – whatever was chosen for a given study).

(ICAN MSJ at 6; Doc. 27, NIH Controverting Statement of Facts ("NCSOF"), Doc. 27-2, Declaration of Chris Roberts ("Roberts Decl.") ¶ 7.) In support of its Motion, ICAN relies almost exclusively on a May 18, 2020 Moderna press release touting "Positive Interim Phase I Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus." (ISSOF at ¶ 16, Doc. 22-2, Ex. B.). ICAN focuses on Moderna's statement that the "data [from Phase I] substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease" as well as the press release's discussion of seroconversion, binding antibody levels, neutralizing antibody titers, immunogenicity data, and immune responses, as well as "a viral challenge study in mice" all of which ICAN contends relate to efficacy. (ICAN CMSJ & Resp. at 9-11; ISOF ¶¶ 17-19.) However, ICAN does not cite any evidence to support the argument that these terms address efficacy. Meanwhile, NIH sufficiently explains that these terms address the Vaccine's immunogenic capability, specifically that many vaccines, such as the HIV vaccines, generate an immune response but do not protect against the disease. (Roberts Decl. ¶ 9.) NIH further provides multiple articles that explain the difference between efficacy and immunogenicity in vaccinology. (NCSOF ¶ 14; Doc. 27-3, Attach. B.) Here, the evidence produced shows Phase I tested the Vaccine's safety as well as whether it could produce an immune response but did not test for effectiveness. Indeed, the Phase I study is titled "Phase I, Open-Label, Dose-Ranging Study

of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults ("Phase I")," and the Moderna press release only mentions "efficacy" when explaining in its "Forward Looking Statement" that "efficacy of mRNA-1273 has not yet been established." (NSOF ¶ 4; Ex. 1 ¶ 12; NCSOF ¶ 14.)

ICAN additionally contends that efficacy data always includes immunogenicity data and thus the immunogenicity data was responsive to the Request. (ICAN Reply at 6-7.) However, ICAN does not provide declarations or articles in support. Rather, it provides excerpts from four NIH peer reviewed publications that each use the phrase "efficacy, including immunogenicity." (ICAN Reply at 7.) This evidence is insufficient to overcome NIH's evidence distinguishing efficacy from immunogenicity. For one, ICAN does not contend that the publications relate to vaccinology. Moreover, the publications do not automatically lead to the conclusion that efficacy data always includes immunogenicity data. At least two of the publications contain language in other sections that suggests that the two are, or at the least can be, mutually exclusive. *See, e.g.* https://link.springer.com/article/10.1007/s10067-019-04496-3 ("comparative clinical tests have been performed in the most sensitive environments with potential differences in safety, efficacy, and immunogenicity"); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3604642/ ("[C]linical trials evaluating residual uncertainty are usually focused on safety and/or immunogenicity and to a lesser extent on sensitive efficacy end points."). At most, these unrelated articles illustrate that at times trials for immunogenicity overlap with trials for efficacy and also may overlap with trials for safety. *See, e.g.* https://link.springer.com/article/10.1007/s10067-019-04496-3 (To assess the potential clinical impact of Anti-Drug Antibodies, immunogenicity assessments are performed in conjunction with pharmacokinetic, safety, and efficacy assessments with all the data considered.").

Therefore, the Court finds ICAN's reliance on the press release and NIH publications misplaced and unconvincing. Because efficacy and immunogenicity are distinguishable and NIH did not test for efficacy until after the Request, NIH's decision to

not search for or produce documents relating to efficacy was reasonable. *Hamdan*, 797 F.3d at 772.

2. ICAN's Reply

NIH contends that ICAN's Reply and subsequent letter to the Court both inappropriately introduce new arguments and new evidence. (NIH Suppl. Resp. to Letter at 4.) The Court agrees. ICAN's Reply contends for the first time that the VRC holds responsive documents and points to VRC's rationale for not searching for documents – it was not the sponsor of the Phase I trial and did not hold any Phase I data – to argue that including Phase I as a search term overly narrowed NIH's search. In order to support this new argument, ICAN argues that the Request asks for all safety and efficacy data regarding mRNA-1273 as well as all information regarding mRNA-1273 and thus because the VRC held the patent and developed the Vaccine, it "without any doubt has "information" related to this vaccine." (ICAN Reply at 5-7.)

Based on this interpretation of the Request, ICAN additionally argues that regardless of whether it was immunogenicity or efficacy data, NIH should have provided all data referenced in the Moderna press release because the Request sought all "information" related to the Vaccine. (ICAN Reply at 7.) While ICAN argues that it should receive immunogenicity data in its Cross-Motion for Summary Judgment, it does not proffer this argument – that the Request for all information invariably included immunogenicity data – until the Reply.

Furthermore, ICAN's interpretation of the Request in its Reply appears to differ from its interpretation in its Cross-Motion for Summary Judgment. There, it appears ICAN understood "data and information" only to apply to the "safety and efficacy" of the Vaccine. In describing its Request in its Cross-Motion for Summary Judgment, ICAN writes that NIH's search "should have covered all data and *information* in NIH's possession *related to the safety and efficacy of the mRNA-1273 vaccine*." (ICAN CMSJ & Resp. at 9.) (emphasis added). Under this interpretation, "information" specifically applies to the "safety and efficacy" of the Vaccine. Earlier in its Cross-Motion for Summary Judgment,

while arguing that the Request was not limited to just Phase I, ICAN stated "The subject of the request is 'all safety and efficacy data and information.'" (ICAN CMSJ & Resp. at 9.) Importantly, ICAN never argued in its Cross-Motion that it was entitled to all information related to the Vaccine. Rather, it tied every argument to its request for safety and efficacy data and information.[2]

ICAN's introduction of these new arguments is prejudicial to NIH. Therefore, the Court declines to consider them and finds that NIH met its obligation to conduct an adequate search for documents responsive to the Request.

B. Information Redacted Pursuant to Exemption 6

Exemption 6 permits the withholding of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6).

NIH moves for summary judgment on the grounds that they have properly invoked Exemption 6 to redact "Phase I patients' personal medical information that was pulled directly from their medical records," including patients' age and adverse events related to the Vaccine. (NIH MSJ at 12.) NIH argues that this information is not only personal and could potentially be used to identify the patients, but also is summarized in other portions of the Report so the public does not have a sufficient interest in the redacted information. ICAN counters and similarly moves on the grounds that without the patients' names or other personally identifying information, the redacted information cannot be used to identify the patients and there are material differences between the summarized information and the redacted information. ICAN contends that NIH cannot show that any minimal privacy interest implicated by the release of the information outweighs the public's interest in understanding NIH's role in funding and running the Phase I trial. (ICAN CMSJ & Resp. at 11-14.)

[2] For example, ICAN argued in its Cross-Motion for Summary Judgment that the viral challenge study in mice related to "safety and efficacy" and thus was responsive to its Request. (ICAN CMSJ & Resp. at 9.) However, under ICAN's arguments proffered in its Reply, ICAN could have simply argued that the study met the definition of all "information related to the Vaccine."

The Ninth Circuit utilizes a two-step test for balancing individual privacy rights against the public's right of access. First, it evaluates whether "disclosure implicates a personal privacy interest that is nontrivial or ... more than [ ] *de minimis*." *Yonemoto*, 686 F.3d at 693 (internal citation and quotation marks omitted). Step one "looks to see whether there is any privacy interest that outweighs the generalized public interest in disclosure that inheres in the FOIA itself, and which is reflected in the presumption in favor of disclosure…" *Id.* at 694. Second, if the agency succeeds in showing that the privacy interest at stake is nontrivial, the requester must illustrate that '"the public interest sought to be advanced is a significant one' — one 'more specific than having the information for its own sake'— and the requested information 'is likely to advance that interest."' *Id.*, *quoting Nat'l Archives and Records Admin. v. Favish*, 541 U.S. 157, 172.

Defendant bears the burden of establishing that the balance tips in favor of privacy, thereby justifying the withholding of the requested material under the asserted exemptions. 5 U.S.C. § 552(a)(4)(B). However, it is Plaintiff's burden to support its claims that disclosure of withheld information advances the public interest. *King v. DOJ*, 830 F.2d 210, 234 (D.C. Cir. 1987). With respect to this disclosure, the public interest is limited to that which "sheds light on an agency's performance of its statutory duty" in order to inform the citizens "about what their government is up to." *DOJ v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 773 (1989). The Ninth Circuit further considers whether it will "appreciably further the public's right to monitor the agency's action," *Forest Serv. Emps.*, 524 F.3d at 1027 (internal quotation marks omitted).

1. Adverse Events

An adverse event is "any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related." (NIH MSJ at 14; NSOF ¶ 41, Ex. 2.) NIH contends that the patients' Adverse Event data should be redacted because "it is a patient's medical diagnosis pulled directly from the patient's medical record." (NIH MSJ at 14; NSOF ¶ 41.) The Court agrees that this information, when connected with an identifiable individual, likely implicates a privacy interest

warranting redaction pursuant to Exemption 6. However, there is no evidence, nor does NIH contend, that the Adverse Event data can be linked to any of the patients who participated in the Phase I trial. *See Ray*, 502 U.S. at 175-176 ("highly personal" information merely implicates a *de minimis* privacy interest where the information cannot be linked to an identifiable individual).

NIH relies on the HIPAA Privacy Rule, 45 C.F.R. § 164.514, to argue that Adverse Event data implicates a non-trivial privacy interest. (NIH CMSJ & Resp. at 11-12.) The Court remains unconvinced. For one, the HIPAA Privacy Rule lists 18 categories of information that must be removed in order for a dataset to be sufficiently de-identified but does not expressly list "Adverse Events" as personally identifying information. 45 C.F.R. § 164.514. Instead, NIH cites a TransCelerate Biopharma Inc. report on "Clinical Data Transparency Initiative De-Identification and Anonymization of Individual Patient Data In Clinical Studies, A Model Approach" that lists "Adverse Events" as an identifier "commonly collected" in clinical studies. (NIH CMSJ & Resp. at 11-12; NSOF ¶ 49, Ex. 1 ¶ 51, Doc. 20-5 at 6.) Importantly, however, NIH never contends that including a patient's Adverse Event data will increase the risk of identifying the patient.[3] Rather, it cites to the HIPAA Privacy Rule and TransCelerate report to illustrate that the Adverse Event data is information "concerning [a patient's] personal matters… typically treated as private information." (NIH Resp. & Reply at 10.) But unless this data is tied to personally identifying information, it does not warrant redaction pursuant to Exemption 6. *Ray*, 502 U.S. at 175-176. Notably, NIH fails to cite a single case where the Court upheld the redaction of information where there was no risk that individuals would be personally identified.

Moreover, the public has an interest in the disclosure of the Adverse Event data. NIH argues that because it did not provide care or directly collect data from the patients, the Adverse Event data would not shed light on the NIH's activities. The Court disagrees.

[3] This differs from NIH's argument that Age data should not be included, discussed *infra*, where NIH expressly contends that the inclusion of Age data will make it easier to identify individual patients. (NIH MSJ at 15; NSOF ¶ 55.)

NIAID funded and led the development of mRNA-1273 and sponsored the Phase I trial (DSOF ¶ 4.) Reviewing the data will allow the public to better understand NIH's actions and bases for its decisions.[4] *Reporters Comm. for Freedom of Press*, 489 U.S. at 773.

NIH further contends that the redacted information is provided elsewhere and thus there is no public interest in its release. Specifically, NIH points to portions of the Report that use "broad technical terms used to categorize the diagnoses for the purposes of analyzing the data" as well as portions of the appendices that "collated, analyzed, and detailed" the Adverse Event Data. (DSOF ¶¶ 45-46.) However, the unredacted data provides substantially less information than the redacted information. NIH acknowledges that redacted Adverse Event data detailing "throbbing pain inside my head behind my eye," is simply coded as "headache." (NIH Resp. and Reply at 11; NCSOF ¶ 26, Declaration of John Beigel ¶ 9.) Where there was a greater individual privacy interest, the unredacted version of the Adverse Event data may have sufficed. However, because of the *de minimis* privacy interest, the public interest in seeing the full data outweighs any individual privacy concerns.

2. If Not Related, Alternative Etiology, Comments, Reasons for Deviation and Deviation Resolution

For the same reasons, NIH cannot articulate a sufficient privacy interest to justify redacting the If Not Related, Alternative Etiology, Comments, or Reasons for Deviation and Deviation Resolution data. The data does not contain personally identifying information and the public has an interest in its release.[5] Therefore, it does not meet the standard for redaction.

[4] ICAN further contends that that there is a sufficient public interest because "states are expected to mandate the vaccine for their residents." (ICAN CMSJ & Resp. at 5.) However, ICAN produces scant evidence, citing only a New York State Bar Association report and a draft of a bill introduced in the New York assembly, to support such a broad assertion.

[5] NIH contends that the public's interest in the release of the "If Not Related, Alternative Etiology" data is particularly low because that data details patients' symptoms and conditions unrelated to the Vaccine. (NIH MSJ at 14-15.) However, even if the symptoms are not caused by the vaccine, the data is still part of the Vaccine trial at issue.

3. Age

Unlike the other categories of redacted information, NIH contends that the Age data is personally identifying information. However, it fails to support the assertion with evidence. Rather, NIH simply concludes that because there are only 85 patients, publicizing their age will lead to their identification. (NIH MSJ at 15.) The Court is skeptical that age alone could identify an individual without more information. There are millions of people of each age currently living in the United States. Without additional evidence, NIH's conclusory statement is insufficient to show that age constitutes a non-trivial privacy interest.

Similar to the other Phase I data, the public has an interest in the ages of the patients. NIH argues that the privacy interest outweighs the public interest because the Report provides "specific age data" in other portions of the Report. However, the Report lists the unredacted age data in broad numerical ranges such as "18-55," and "56-70." (NSOF ¶ 55, Ex. 1, Declaration of Gorka Garcia-Malene ¶ 53.) These ranges do not provide the same information as the specific ages of the trial participants. Because the privacy interest in the Age data is trivial and there is a public interest, the Court finds that the redactions are improper.

For these reasons, the Court will grant ICAN's Cross-Motion for Summary Judgment regarding the redactions pursuant to Exemption 6.

IT IS THEREFORE ORDERED granting in part and denying in part NIH's Motion for Summary Judgment (Doc. 18). NIH is entitled to summary judgment regarding ICAN's claim regarding the adequacy of its search.

IT IS FURTHER ORDERED granting in part and denying in part ICAN's Cross-Motion for Summary Judgment (Doc. 21). ICAN is entitled to summary judgment regarding the redactions pursuant to Exemption 6.

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IT IS FURTHER ORDERED that NIH shall remove the redactions at issue and produce the Safety Report to ICAN within three weeks of this Court's Order.

IT IS FURTHER ORDERED directing the Clerk of the Court to enter judgment accordingly and close this matter.

Dated this 24th day of June, 2021.

Honorable John J. Tuchi
United States District Judge