UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, and COMMONWEALTH OF PENNSYLVANIA, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, UNITED STATES DEPARTMENT OF HEALTH AND	NO. 1:23-CV-3026-TOR ORDER GRANTING IN PART PLAINTIFFS' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

BEFORE THE COURT is Plaintiff States' Motion to Supplement the Administrative Record (ECF No. 133). The matter was submitted for consideration without oral argument. The Court has reviewed the record and files herein, and is fully informed. For the reasons discussed below, Plaintiff States' Motion to Supplement the Administrative Record (ECF No. 133) is **GRANTED IN PART**.

BACKGROUND

This case concerns federal regulation of mifepristone, a drug used to assist with the termination of early intrauterine pregnancy. The motion pending before the Court arises out of Plaintiffs' request to complete and/or supplement the administrative record. *See* ECF No. 133. For purposes of contextualizing the parties' arguments, the Court reviews the underlying facts and procedural history of the litigation.

In 2000, the United States Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services (HHS), approved the distribution of mifepristone under Subpart H of the Food, Drug, and

Cosmetic Act (FDCA). ECF No. 35 at 23-24, ¶ 87.[1] Under Subpart H, FDA imposed certain restrictions on the prescription and distribution of mifepristone to assure safe use. *Id.*; *see also* 21 C.F.R. § 314.520(a) (2023) ("If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product."). These restrictions included, *inter alia*:

> (1) an "in-person dispensation requirement," under which the drug could only be administered and dispensed in a hospital, clinic, or medical office, by or under the supervision of a physician-provider;
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> (2) a "prescriber certification requirement," under which providers could not prescribe the drug without first attesting to their clinical abilities and agreeing to various reporting requirements in a signed form retained by the manufacturer; and
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> (3) a "patient agreement form requirement," under which prescribers and patients were required to review and sign a form which included information about the mifepristone regimen and risks, and under which the prescriber was required to (a) retain one copy of the form in the patient's medical record and (b) provide the patient with one separate copy.

[1] Mifepristone was approved for distribution under the brand name "Mifeprex." ECF No. 35 at 2, ¶ 2. A generic version was also approved in 2019. *Id.* at 32, ¶ 103. Mifepristone is used in a two-dose regimen with misoprostol, a separate FDA-approved drug, to terminate a pregnancy. *Id.* at 21, ¶ 82.

ECF No. 35 at 23-24, ¶ 87.[2]

Through the Food and Drug Administration Amendments Act (FDAAA) of 2007, Congress replaced Subpart H with the Risk Evaluation and Mitigation Strategies (REMS) statute. ECF Nos. 35 at 25, ¶ 89; 51 at 6-7; *see also* 21 U.S.C. § 355-1(a)(1) (authorizing the Secretary of FDA to require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug"). The statute lists six factors for FDA to consider in deciding whether a REMS is necessary. *See* 21 U.S.C. § 355-1(A)-(F). Additionally, Congress licensed FDA to require that a REMS include certain "elements to assure safe use" (ETASU). 21 U.S.C. § 355-1(f). ETASU are required upon a determination by the Secretary that the drug has been proven effective, "but is associated with a serious adverse drug experience," and therefore can only be approved with certain restrictions in place to mitigate the "serious specific risk[s]" of the drug. *Id.*

[2] Related restrictions included, for instance, that the regimen could only be administered within a 49-day gestational period, and that both mifepristone and misoprostol must be administered under medical supervision over the course of two separate, in-person office visits and one in-person follow-up visit. ECF No. 51-5 at 4. These restrictions were later amended to extend the gestational period to 70 days and to require only one in-person visit. *Id.* at 4-5.

With the enactment of the FDAAA, Congress determined that all drugs previously approved pursuant to Subpart H would be deemed to have a REMS in place, with any restrictions under Subpart H qualifying as ETASU. ECF No. 51 at 8 (citing Pub. L. 110-85, tit. IX, § 909(b)(1)). Thus, mifepristone was subject to a qualifying REMS, and the three above-mentioned Subpart H restrictions on its distribution remained in place as ETASU. *Id.*; *see also* ECF No. 35 at 25, ¶ 89.

Since 2007, FDA has occasionally reevaluated the necessity of a REMS and ETASU for mifepristone.[3] ECF No. 51 at 9. In 2016, the agency notably concluded that "known serious risks occur rarely" and predicted that because "the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low." ECF No. 35 at 30, ¶ 100. As a result, FDA made several changes to the REMS, including updating the prescriber agreement and allowing non-physician health care providers who meet certification requirements to dispense the drug. ECF No. 51-5 at 4-5.

On May 7, 2021, FDA announced it would undertake a full review of the mifepristone REMS. ECF No. 35 at 32-33, ¶¶ 104-105. In a December 16, 2021 letter addressing a citizen petition brought by the American Association of Pro-

[3] As of 2019, the REMS and ETASU apply to both Mifeprex and the generic version of mifepristone. ECF No. 35 at 32, ¶ 103.

Life Obstetricians and Gynecologists and American College of Pediatricians, FDA advised that it was making several changes to the REMS, including (1) suspending the in-person dispensation requirement[4] and (2) promulgating a new pharmacy certification requirement, under which pharmacies may dispense mifepristone upon the condition that they first obtain special certification from drug sponsors.[5] ECF No. 1-13 at 2-5. Both the prescriber certification requirement and the patient agreement requirement remained in force. ECF No. 35 at 37, ¶ 116; 39 at ¶ 121. As a result of this review, FDA issued an updated mifepristone REMS on January 3, 2023. *See* ECF No. 1-13.

On February 23, 2023, Plaintiffs, comprised of seventeen States and the District of Columbia, sued Defendants in this Court challenging FDA's

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[4] Due to the COVID-19 public health emergency, FDA had previously been enjoined from enforcing the in-person dispensation requirement by a federal court in Maryland. *See Am. Coll. Of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The United States Supreme Court granted the FDA's request for a stay of the injunction in January 2021. *FDA v. Am. Coll. Of Obstetricians & Gynecologists*, 141 S.Ct. 578 (2021).

[5] The prior REMS required that mifepristone could only be dispensed by a provider in a healthcare clinic. ECF No. 35 at 38, ¶ 118.

promulgation of the 2023 REMS as unlawful under the Administrative Procedure Act (APA) and U.S. Constitution. ECF Nos. 1; 35 at 88-90 (amended complaint). Plaintiffs asked the Court to issue a preliminary injunction (1) "affirming FDA's original conclusion that mifepristone is safe and effective," (2) enjoining any actions by Defendants to remove mifepristone from the market, and (3) enjoining the January 2023 REMS and ETASU—or any REMS and ETASU—from taking effect. ECF Nos. 3 at 5; 60 at 10. On April 7, 2023, the Court preliminarily enjoined Defendants from altering the status or rights of the parties under the operative REMS. *See* ECF No. 80; *see also Washington v. United States Food & Drug Admin.*, 668 F. Supp. 3d 1125, 1143 (E.D. Wash. 2023), *opinion clarified*, 669 F. Supp. 3d 1057.

Plaintiffs now move to supplement the record, claiming that in the course of designating the administrative record Defendants have intentionally omitted (1) a 2022 citizen petition by the American College of Obstetricians and Gynecologists (ACOG) and 48 other organizations; (2) a letter by FDA to the ACOG denying the citizen petition; (3) documents and studies cited within the ACOG citizen petition; and (4) the "Turnaway Study," a longitudinal study on abortion access. ECF No. 133 at 5. Plaintiffs claim that FDA considered these materials in the course of deciding whether to promulgate the 2023 REMS, or that, alternatively, supplementation of these extra-record documents is appropriate. *Id.*

DISCUSSION

I. Extra-Record Evidence

The APA empowers the judiciary to review and set aside agency action that is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Judicial review of agency action is necessarily circumscribed: a court "may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.").

To deter *de novo* judicial review and *post hoc* justifications for administrative action, the APA instructs courts to review "the whole record or those parts of it cited by a party." 5 U.S.C. § 706; *see Dep't of Com. v. New York*, 588 U.S. ----, 139 S.Ct. 2551, 2573 (2019) (explaining that "a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record . . . [because] judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government") (quoting *Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 268, n.18 (1977)). The "whole" administrative record "consists of all

documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Thompson v. U.S. Dep't of Lab.*, 885 F.2d 551, 555 (9th Cir. 1989) (internal quotations and citations omitted) (emphasis omitted). Absent "clear evidence to the contrary," the agency's designation of the administrative record is entitled "to a presumption of completeness." *In re United States*, 875 F.3d 1200, 1206 (9th Cir.), *vacated on other grounds*, 583 U.S. 29 (2017); *see also Walter O. Boswell Mem. Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision.").

Of course, exceptions exist to this general rule. *Thompson*, 885 F.2d at 555 ("The whole administrative record . . . is not necessarily those documents that the *agency* has compiled and submitted as 'the' administrative record.") (internal quotations and citations omitted) (emphasis in original). Where a party identifies "omitted materials with sufficient specificity" and "reasonable, non-speculative grounds for the belief that the documents were considered by the agency and not included in the record," the court may order the agency to complete the record. *Oceana, Inc. v. Pritzker*, No. 16-cv-06784-LHK (SVK), 2017 WL 2670733 at *2 (N.D. Cal. June 21, 2017) (internal quotations and citations omitted); *see also Xerces Soc'y for Invertebrate Conservation v. Shea*, --- F. Supp. 3d ----, 2023 WL

4941221, at *5 (D. Or. July 17, 2023). It is insufficient for a party to merely assert that the missing "documents were relevant, were before or in front of the agency[,] and not included in the record." *Xerces Soc'y*, 2023 WL 4941221 at *5; *see, e.g.*, *S.F. Bay Conservation & Dev. Comm'n v. United States Army Corps of Eng'rs*, No. 16-cv-05420-RS(JCS), 2018 WL 3846002 at *4 (N.D. Cal. Aug. 13, 2018) ("The fact that the documents might be relevant to the [Corps'] decisions does not establish that the Corps actually considered them, either directly or indirectly."). A plaintiff may "also rebut the presumption of completeness by showing that the agency applied the wrong standard in compiling the record," such as where the agency excludes documents because "they did not 'form the basis' for the agency's determination [as opposed to the indirect versus direct consideration standard]." *Oceana, Inc.*, 2017 WL 2670733 at *2 (internal citation omitted).

Alternatively, in narrow circumstances, supplementation of extra-record evidence may be appropriate where:

> [A]dmission of that evidence (1) is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) is necessary to determine whether the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith.

San Luis & Delta-Mendota Water Auth. v. Locke, 776 F.3d 971, 992 (9th Cir. 2014) (internal quotations and citations omitted); *accord Lands Council v. Powell*,

395 F.3d 1019, 1030 (9th Cir. 2005). Parties seeking to supplement the administrative record bear a "heavy burden to show that the additional materials sought are necessary to adequately review the [agency's] decision." *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010).

Here, Plaintiffs assert that supplementation is warranted because it is "necessary to determine whether the agency has considered all relevant factors and has explained its decision." *San Luis.*, 776 F.3d at 992. Of the four factors, this variable is the most exacting. *Id.* at 993. The Ninth Circuit has warned that "the exception does not permit district courts to use extra-record evidence to judge the wisdom of the agency's action" or to "question[ ] the agency's scientific analyses or conclusions," but instead is intended "only to help the court understand whether the agency complied with the APA's requirement that the agency's decision be neither arbitrary nor capricious." *Id.* at 993. Therefore, a court may supplement the record when the agency entirely "fails to consider a general subject matter," but should stay its hand when "the record contains sufficient information to explain how the agency used the information before it and why it reached its decision." *ForestKeeper v. La Price*, 270 F. Supp. 3d 1182, 1228 (E.D. Cal. 2017) (internal quotations and citations omitted) (cleaned up). Documents post-dating the agency decision may not be included within the record. *Southwest Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996).

Bearing these legal principles in mind, the Court turns to the substance of Plaintiffs' arguments.

II. Citizen Petition, Denial Letter & References

Plaintiffs request that (1) the 2022 citizen petition by the ACOG, (2) FDA's letter to the ACOG denying the citizen petition, and (3) all sources cited within the petition be included within the administrative record. ECF No. 133 at 7.

Plaintiffs submit that this Court has already found the petition and denial letter were "before" FDA at the time of its decision. ECF No. 133 at 6. Specifically, in resolving whether Plaintiffs had exhausted their administrative remedies in its prior Order entering a preliminary injunction, this Court wrote:

> In 2020, fifteen Plaintiff States asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. In 2021, FDA conducted a "full review" of REMS, including information about comparator drugs with mifepristone. *In 2022, the ACOG and other medical and professional healthcare organizations petitioned FDA, in part, to eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage management*.
>
> Based on the information and requests already put forth before FDA, FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition. Thus, the Court finds that administrative exhaustion through a citizen petition on the January 2023 REMS would be futile.

Washington, 668 F. Supp. 3d at 1139 (emphasis added).

Plaintiffs also contend that FDA considered the petition because of the denial letter itself. ECF No. 133 at 7-8. Plaintiffs state that the petition was denied on the same day that the 2023 REMS were promulgated, thereby evincing that the petition was directly considered by FDA in reaching a decision. *Id.* at 9.

For its part, FDA protests that neither its denial letter nor this Court's prior Order suffice to show it considered the citizen petition in promulgating the 2023 REMS. ECF No. 139 at 8-9. FDA further insists that the petition is irrelevant to the REMS, as the petition advocated for the unauthorized use of mifepristone for miscarriage management, whereas the 2023 REMS dealt with the authorized use of mifepristone for termination of early intrauterine pregnancy. *Id.* at 14.

The Court agrees with Plaintiffs that the ACOG citizen petition and denial letter should be included within the administrative record. To be clear, the Court's earlier determination on the issue of exhaustion called for the application of a different legal standard than the one at issue here. For these purposes, however, Plaintiffs have sufficiently identified specific documents (that is, the petition and letter) and reasonable, non-speculative grounds for their belief that those materials were considered by FDA in the course of its decision-making process. *Oceana, Inc.*, 2017 WL 2670733 at *2. Chief among those reasons were the facts that the denial letter was conspicuously issued on the same day the 2023 REMS were

promulgated and the fact that the amended REMS addresses issues within the same subject matter as the petition.

Regarding FDA's argument that the citizen petition is irrelevant, the Court agrees that the primary "thesis" of the petition was that miscarriage management should be added as an indication to the drug's label and that FDA should eliminate or modify the REMS for that purpose. However, the petition also advanced a secondary argument that the REMS should be done away with entirely, including with respect to the use of mifepristone for termination of early pregnancy. *See* ECF No. 61-1 at 13 (recommending "that the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent"); 16 (arguing that early "research suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden access"); 18 (discussing a New England Journal of Medicine study on the effect of removing all restrictions on mifepristone prescriptions for abortion in Canada). Therefore, Plaintiffs have demonstrated to the Court's satisfaction that the 2022 ACOG citizen petition and denial letter were "before" FDA at the time it promulgated the 2023 REMS and that FDA directly or indirectly considered such evidence in amending the REMS. [6]

[6] FDA also implies, but does not explicitly argue, that the petition was not "before" it at the time of its decision, because it rendered its decision on the 2023

Plaintiffs also request that FDA be ordered to produce the 52 documents and studies cited *within* the citizen petition. ECF No. 133 at 8. Plaintiffs argue that the cited works should be disclosed primarily for consistency, because FDA has produced the references of other record-produced documents. *Id.* Alternatively, Plaintiffs claim that supplementation is appropriate because it will help the Court evaluate whether FDA "failed to consider an important aspect of the problem": whether lifting the REMS and ETASU would impact mifepristone's safety profile. *Id.* at 9-11; ECF No. 141 at 10.

Plaintiffs have not met their burden to show the record is incomplete with respect to the citations within the citizen petition. Even if the Court were to say those documents were "before" FDA, Plaintiffs have not offered any evidence

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REMS when it ruled on the December 16, 2021 citizen petition brought by the American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians. *See* ECF No. 139 at 6. The Court declines to engage with this argument, as the amended REMS were not promulgated until January 2023, and other materials within the designated record also post-date the December 16, 2021 letter. *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 239-31 (1980) (listing factors for the court to consider in determining the finality of agency action).

suggesting the documents were considered directly or indirectly by the agency. The fact that the agency elected to include other, referenced documents as part of the administrative record is not dispositive of whether the specific references within the citizen petition were considered.

On the whole, Plaintiffs' alternate claim that the citations should be supplemented because FDA failed to consider a general subject matter also fails. Plaintiffs correctly point out that the underlying Order on Plaintiffs' motion for a preliminary injunction held that FDA failed to assess whether mifepristone qualifies for REMS and ETASU based on the statutory criteria. *Washington*, 668 F. Supp. 3d at 1141. However, Plaintiffs were not specific about the content of the citations, many of which seem to concern mifepristone's safety profile with respect to miscarriages rather than abortion. *See, e.g.*, 61-1 at 22-28, ¶¶ 5-7, 11-19, 23-29, 32, 45. It seems that allowing supplementation with respect to these citations would serve more as a vehicle for the Court to rely upon extra-record evidence to" judge the wisdom of [FDA's] action" than it would assist the Court with understanding whether FDA acted arbitrarily and capriciously in promulgating the 2023 REMS. *San Luis*, 776 F.3d at 993; *see also Save the Colorado v. United States Dep't of Interior*, 517 F. Supp. 3d 890, 898-99 (D. Ariz. 2021) (declining to allow supplementation of documents referenced within a produced document and reasoning that "[r]equiring such a sweeping application of what was indirectly

before the agency would undermine the value of judicial review"). The Court finds that Plaintiffs have not met their heavy burden to show that the majority of these references should be included within the administrative record.

There is one exception. The citizen petition cited and discussed at some length a 2022 study by the New England Journal of Medicine on Canada's deregulation of mifepristone. ECF No. 61-1 at 18. The study concluded that lifting restrictions on the drug in Canada did not impact its safety profile. ECF No. 61-1 at 18. In their motion, Plaintiffs press that the record needs to be supplemented with this specific study because it will show FDA overlooked evidence showing eliminating the REMS would not impact the safety of mifepristone. ECF No. 141 at 10-11.

The Court agrees that this evidence is relevant and may assist the Court with understanding whether, in fact, FDA acted arbitrarily and capriciously in promulgating REMS and ETASU for mifepristone. *See* 21 U.S.C. § 355-1(a)(1)(E) ("[T]he Secretary shall consider . . . [t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug."). FDA attempts to rebut these arguments by asserting that it did consider evidence relating to Canada's experience. ECF No. 139 at 13. But as Plaintiffs mention, the study cited by Defendants in their 2021 review was limited in scope: it merely compared

the outcomes of telemedicine versus in-person visits for medication abortion in Canada. ECF No. 141 at 11. The 2022 New England study, by contrast, goes directly to Plaintiffs' arguments that the REMS and ETASU should have been eliminated entirely. Admission of this evidence will assist the Court with "develop[ing] a background against which it can evaluate the integrity of [FDA's] analysis." *San Luis*, 776 F.3d at 993. Accordingly, FDA shall produce the citizen petition, denial letter, and New England Journal of Medicine Study on Canada's deregulation of mifepristone.

III. Turnaway Study

As a final matter, Plaintiffs request that the Court order FDA to include the Turnaway Study (Study) with the administrative record. The Study is a longitudinal survey which evaluates and compares "women's psychological well-being 5 years after receiving or being denied an abortion." ECF No. 135 at 7. Plaintiffs argue that the Study should be included because it is cited throughout the produced record (by Plaintiffs' count, up to 35 times), including in a 2016 letter sent by the study's author, Advancing New Standards in Reproductive Health (ANSIRH), to FDA. ECF No. 133 at 5. Plaintiffs contend that this means the Study was "before" FDA, or that, alternatively, supplementation is required. *Id.* at 9, 11. Specifically, Plaintiffs press that inclusion of the Study is necessary because it again will highlight FDA's failure to consider an important aspect of the

problem; that is, whether the REMS and ETASU restrictions create "undu[e] burdens[ ] on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas." 21 U.S.C. § 355-1(f)(2)(C)(ii).

FDA offers several counterarguments. First, FDA argues that it is unclear what version of the Study Plaintiffs are referring to, writing, "As far as the agency can tell, the Turnaway Study is not a discrete document, but was a multi-year longitudinal study, data from which has been reported at various points in multiple publication." ECF No. 139 at 10. Second, FDA notes that several of the Turnaway publications are included within the administrative record. *Id.* Third, the agency reiterates that the mere citation of documents within a record document does not make the cited document part of the administrative record. *Id.* Separately, regarding Plaintiffs' arguments that the Study should be supplemented if it is not part of the completed record, FDA protests that it *did* include data similar to the Study's findings, which showed that most women who seek abortions are in difficult financial situations and that receiving an abortion improves mental health outcomes for women who desire the procedure. *Id.* at 13-14.

The Court agrees with FDA. As to the issue of completion, Plaintiffs' reply fails to squarely address FDA's concern over which version of the Study is at issue. This runs afoul of the requirement that a party asserting that the record is

incomplete must identify the missing material with specificity. *Save the Colorado*, 517 F. Supp. 3d at 901 (declining to include broad categories of documents which the plaintiff sought to supplement the record with but failed to individually identify). Although the fact that the Study was discussed multiple times in different record documents might give rise to the inference that the agency indirectly considered it, the Court has no way of knowing which version(s) of the Study were discussed in those references. Thus, the Court cannot confidently conclude that the Study was "before" FDA.

The Court also declines to supplement the record with the Study. As mentioned, the exceptions to the general rule against supplementing extra-record evidence are narrowly construed. Unlike the conclusions of the New England Study regarding the propriety of full deregulation and the effect it would have on the safety profile of the drug, which were not identified anywhere within the record by FDA, here the agency noted numerous places in the record where it examined data related to the mental health impacts of abortion on women and the impact of receiving a wanted abortion on low-income women, including in ANSIRH's letter to FDA. ECF No. 139 at 14; *see also* ECF No. 142-1. The Study would be repetitive of these findings, and other reported documents which discuss the Study's findings.

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ACCORDINGLY, IT IS HEREBY ORDERED:

Plaintiffs' Motion to Supplement the Administrative Record (ECF No. 133) is **GRANTED IN PART**. As set forth herein, the 2022 ACOG citizen petition, letter denying the 2022 ACOG citizen petition, and New England Journal of Medicine study on Canada's deregulation of mifepristone discussed in the citizen petition shall be produced forthwith as part of the Administrative Record.

The District Court Executive is directed to enter this Order and furnish copies to counsel, including those attorneys who have not signed up for electronic filing and service. *See* Gen Order No. 100-04-1.

DATED March 8, 2024.

THOMAS O. RICE
United States District Judge