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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026-TOR PLAINTIFF STATES' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD 02/20/2024 Without Oral Argument

I. INTRODUCTION

This case is about whether the Food and Drug Administration (FDA) acted arbitrarily, capriciously, or contrary to law when it decided—against the overwhelming weight of the evidence before it and the professional medical consensus—to restrict access to mifepristone by re-imposing a set of burdensome and unnecessary restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). The REMS includes Elements to Assure Safe Use (ETASU), mandatory restrictions meant to be reserved in rare cases for exceptionally dangerous drugs. Despite mifepristone's extraordinarily strong safety record, FDA irrationally and unlawfully singled this medication out for the most onerous form of restrictions.

To facilitate meaningful judicial review under the Administrative Procedure Act (APA), FDA must submit the *whole* administrative record—i.e., all materials that were before FDA when it decided to impose the REMS, including evidence that contradicts FDA's position. Here, however, FDA has submitted an incomplete record. To begin, glaringly absent is a key document that this Court has already found was "before FDA": a 2022 citizen petition filed by the American College of Obstetricians and Gynecologists (ACOG) and 48 other signatories, formally asking FDA to lift the REMS based on abundant evidence that these restrictions are unnecessary and impede access to an essential medication. ECF No. 80 at 17. After "carefully consider[ing]" ACOG's citizen petition, FDA denied it on the very same day that it imposed the current REMS: January 3, 2023. ECF No. 1-20 at 2. FDA's denial letter is missing from the record, too.

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Additionally, the produced record excludes the Turnaway Study, a landmark study on abortion access that is cited at least 35 times within the produced record, including in a 2016 letter to FDA signed by the very entity that conducted the study. This study was before FDA and was—or should have been—considered.

The Plaintiff States therefore request that the Court order FDA to supplement the filed record to include the ACOG citizen petition and the documents cited therein, FDA's letter denying the ACOG citizen petition, and the Turnaway Study.

II. BACKGROUND

A. The Court's Preliminary Injunction Ruling

This lawsuit alleges, *inter alia*, that the mifepristone REMS is contrary to law, exceeds FDA's statutory authority, and is arbitrary and capricious. ECF No. 35 at 88-89. In April 2023, this Court preliminarily enjoined FDA from altering the status quo and rights as it relates to the availability of mifepristone in the Plaintiff States under the current REMS. ECF No. 80. In its order, the Court addressed the States' argument that they were not required to petition FDA before filing suit because they and others had already done so, and recognized that:

> 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. ECF No. 60 at 5. In 2021, FDA conducted a "full review" of REMS, including information about comparator drugs with mifepristone. ECF No. 60 at 7. In 2022, the ACOG and other medical and professional healthcare access organizations petitioned FDA to, in part, eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage

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> management. ECF Nos. 35 at 47, ¶ 139; 60 at 4; 61-1. FDA rejected ACOG's citizen petition. ECF No. 35 at 51, ¶ 144.

Id. at 16-17. Thus, the Court concluded: "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." *Id.*

As to the merits, the Court explained that FDA may impose a REMS if it "determines, after considering six factors, it is 'necessary to ensure that the benefits of the drug outweigh the risks of the drug.'" *Id.* at 18–19 (quoting 21 U.S.C. § 355-1(a)(1)). "Moreover, a REMS may include . . . [ETASU] due to a drug's 'inherent toxicity or potential harmfulness' if the drug has 'been shown to be effective, but is associated with a serious adverse drug experience, [and] can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug.'" *Id.* at 19 (quoting 21 U.S.C. § 355-1(f)(1)(A)).

Based on the record at that stage, the Court found, *inter alia*, that "FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth" in the governing statutes. *Id.* at 21. Thus, "it appears FDA failed to consider an important aspect of the problem." *Id.* (citing *Turtle Island Restoration Network v. U.S. Dep't of Com.*, 878 F.3d 725, 732 (9th Cir. 2017)). Further, responding to FDA's contention that it "need only determine whether modifications are appropriate" without addressing whether mifepristone actually qualifies for ETASU, the Court found that "it would be contrary to the plain

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language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part" based on statutorily-established criteria. *Id.* at 20-21.

B. FDA's Production of the Administrative Record

On September 1, 2023, FDA notified the Plaintiff States that its production of the administrative record was complete, and filed an Index of the same. ECF No. 127; Beneski Decl. ¶ 3. The produced record consists of approximately 5,099 pages, and includes some of the documents that the Court recognized were "before FDA" when it decided to impose the current REMS restrictions. *See* ECF No. 80 at 16-17; Williams Decl. ¶ 5. However, the produced record did not include the 2022 citizen petition filed by ACOG and 48 other organizations (ECF No. 61-1), or FDA's January 3, 2023, letter denying the petition (ECF No. 1-20). *Id.* ¶ 6. Nor did it include the Turnaway Study, a landmark study that is cited at least 35 times within the produced record, including in a 2016 letter to FDA signed by the entity that conducted the study and 29 other organizations. *Id.*; *see* ECF No. 1-9 at 3; ECF No. 35 ¶ 95 & n.19.

After comprehensively reviewing the produced record, in December 2023, the Plaintiff States advised FDA that these and other documents were missing, and requested that FDA supplement the record accordingly. Beneski Decl. ¶ 4. FDA agreed to add some of the missing documents to the record, but refused to add the 2022 ACOG citizen petition, the documents cited therein, the denial letter, or the Turnaway Study. *Id.* ¶ 5.

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III. ARGUMENT

A. Legal Standard

Judicial review of an agency decision "is based on the administrative record and the basis for the agency's decision must come from the record." *Ass'n of Irritated Residents v. E.P.A.*, 790 F.3d 934, 942 (9th Cir. 2015). Judicial review is based on "the whole record[.]" 5 U.S.C. § 706. The "whole" 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). "[T]he whole record is not necessarily those documents that the agency has compiled and submitted as 'the' administrative record; the court must look to all the evidence that was before the decision-making body[.]" *Pub. Power Council v. Johnson*, 674 F.2d 791, 794 (9th Cir. 1982) (internal quotation marks omitted). "An incomplete record must be viewed as a fictional account of the actual decisionmaking process." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993) (citation and internal quotation marks omitted).

Moreover, supplementation is also appropriate when, *inter alia*, "necessary to determine if the agency has considered all factors and explained its decision[.]" *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010); *accord Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). Because "[a]n agency's action may be arbitrary and capricious if it can be shown that 'the agency . . . entirely failed to consider an important aspect of the problem, [or]

offered an explanation for its decision that runs counter to the evidence before the agency,' . . . documents that were *not* relied upon by a decisionmaker, or evidence relating to such documents and their non-consideration, have been held to be necessary elements of an administrative record." *Trout Unlimited v. Lohn*, No. C05-1128C, 2006 WL 1207901, at *3 (W.D. Wash. May 4, 2006) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

B. ACOG's Citizen Petition Was Before FDA When It Imposed the REMS

This Court has already recognized that ACOG's 2022 citizen petition, which asked FDA to remove the REMS as medically unnecessary and unduly burdensome, was "before FDA" when FDA decided to re-impose a REMS with ETASU on mifepristone in 2023. ECF No. 80 at 17. As the Court concluded: "Based on the information and requests already put forth before FDA"—specifically including the 2022 petition filed by "ACOG and other medical and professional healthcare access organizations" (ECF No. 61-1)—"FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." ECF No. 80 at 17.

For the same reason, FDA also cannot credibly argue that ACOG's citizen petition was somehow not before the agency when it made its decision. To be sure, FDA denied the petition. *See id.*; ECF No. 1-20 at 2. But FDA's disagreement with ACOG does not justify excluding ACOG's petition from the record. To the contrary, "the court must look to all the evidence that was before" FDA when it made its decision, *Pub. Power Council*, 674 F.2d at 794, which "includes evidence

contrary to the agency's position." *Thompson*, 885 F.2d at 555. FDA's "careful[] consider[ation]" of ACOG's petition, ECF No. 1-20 at 2—not its rejection of ACOG's request—is dispositive. The petition was undoubtedly before the agency, and the record should be supplemented accordingly.

Additionally, the record should be supplemented to include the 52 studies and other documents ACOG cited in its petition to support its request to remove the REMS. Just as the petition itself was "before the decision-making body," so too were the materials cited in the petition—in the same way that cases cited in a legal brief are before the court. The produced record itself confirms this by including studies and other documents that are cited within record documents. For example, the filed record includes the 2020 letter to FDA submitted by 15 Plaintiff States, along with the five documents cited therein. *See* ECF No. 127 at 20-21 (Index listing 2021 REMS 000035-040 with five sub-listings). Similarly, the filed record includes a 2021 letter from Dr. Graham Chelius to Acting FDA Commissioner Dr. Janet Woodcock, along with the 22 documents cited therein. *See id.* at 31-33 (Index listing 2021 REMS 001159-1167 with 22 sub-listings). The 52 citations within the ACOG citizen petition provide the evidentiary support for the signatories' request to lift the REMS, and that evidence was "before FDA" just as the petition itself was.

Finally, this Court has also recognized that FDA "rejected ACOG's citizen petition." ECF No. 80 at 17. FDA's January 3, 2023 letter denying ACOG's request to lift the REMS—which was issued on the very same day the FDA imposed the

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current REMS—confirms that FDA in fact "carefully considered" ACOG's petition. ECF No. 1-20 at 2. While the filing of a formal citizen petition with the FDA is enough, on its own, to establish that the petition was "before FDA," the denial letter leaves no doubt that the petition was directly considered. But the denial letter, too, is missing from the filed administrative record.

The ACOG citizen petition, the documents cited therein, and the denial letter are all part of the "whole" administrative record. Supplementation is warranted.

C. The Turnaway Study Was Before FDA

The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSRH), examined the effects on people's lives of being denied a wanted abortion. ECF No. 1-9 at 3. This landmark study, which examines the consequences of restricting abortion access for people's health and well-being, is cited extensively throughout the produced record, appearing in at least 35 citing references. Williams Decl. ¶ 6.c. Among them is a letter to FDA from 30 signatories, including ANSRH itself, citing the Turnaway Study as evidence in urging FDA to lift the REMS. *Id.*; ECF No. 1-9; ECF No. 35 ¶ 95 & n.19. For the same reasons discussed above, the Turnaway Study was therefore before FDA when it imposed the REMS.

D. The Missing Documents Are Necessary for Judicial Review

Even if the Court were to reconsider its prior conclusion that ACOG's citizen petition was "before FDA" and find that FDA did not "directly" or even "indirectly" consider the petition and the related documents, the Court should still

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supplement the record to include these and the other missing documents because they will help in evaluating the Plaintiff States' APA claims—including whether FDA "considered all factors and explained its decision[.]" *Fence Creek Cattle Co.*, 602 F.3d at 1131. "[D]ocuments which may demonstrate that the Government ignored relevant factors" in an APA case "are appropriately part of the administrative record[.]" *High Sierra Hikers Ass'n v. U.S. Dep't of the Interior*, No. C-09-4621 JCS, 2011 WL 2531138, at *9 (N.D. Cal. June 24, 2011); *Lands Council*, 395 F.3d at 1030 ("extra-record evidence" should be admitted when "necessary to determine whether the agency has considered all relevant factors and has explained its decision" (citation and internal quotation marks omitted)).

Here, the Plaintiff States will argue—as the Court has already preliminarily found—that FDA "failed to consider an important aspect of the problem" and failed to "consider arguments that mifepristone's REMS and ETASU should be removed in whole or in part . . . ." ECF No. 80 at 20-21. ACOG's citizen petition cited extensive evidence that the mifepristone REMS is unnecessary for safety or risk management, that it imposes burdens that disincentivize prescribing, dispensing, and accessing the medication, and that removing the restrictions would not harm patient safety. *See generally* ECF No. 61-1. As one key example, ACOG's petition cited a study published in the New England Journal of Medicine that, as ACOG explained, demonstrated "no increase in complications from mifepristone use" after Canada "removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like

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any other drug . . . .” *Id.* at 18 & 29 n.52. This study examined data from the 10-month period in Canada when mifepristone was distributed under “REMS-like restrictions” and the 28-month period when it was distributed without such restrictions, and found “no difference” in the rates of complications or serious adverse events. *Id.* FDA was made aware of this study through ACOG’s citizen petition and should have considered it before imposing the REMS in 2023.

Likewise, the Turnaway Study, which is cited throughout the produced record, shows that “the majority of people who seek abortion care are already in difficult financial situations,” meaning the unnecessary REMS restrictions have disproportionate impacts on these patients. ECF No. 1-9 at 3-4. And as a study within the record concludes based on Turnaway Study data, “women receiving wanted abortions had similar or better mental health outcomes than those who were denied a wanted abortion.” Williams Decl. Ex. A at 9. FDA should have considered these findings, and their implications for particularly vulnerable patient populations, in light of the statutory requirement that ETASU must not be “unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas,” and must “minimize the burden on the health care delivery system . . . .” 21 U.S.C. §§ 355-1(f)(2)(C)-(D).

Because FDA’s decision to ignore these materials is integral to the Plaintiff States’ claims, supplementation is warranted for this independent reason.

IV. CONCLUSION

The Plaintiff States’ motion to supplement the record should be granted.

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DATED this 19th day of January 2024.

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CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 19th day of January 2024, at Seattle, Washington.

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