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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF STATES' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

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INTRODUCTION

Plaintiffs challenge the Food and Drug Administration's January 2023 approval of modifications to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone for early termination of pregnancy (the Mifepristone REMS Program). On September 1, 2023, FDA produced the administrative record, tallying over 6,000 pages, for this challenged action. Now, Plaintiffs move to supplement the administrative record, ECF No. 133 (Mot.), with (1) documents relating to a citizen petition that FDA did not consider in connection with the challenged agency action and (2) an unspecified document or documents relating to a study, data from which is discussed in various record materials. The Court should deny the motion.[1]

BACKGROUND

On May 7, 2021, FDA announced a review of the Mifepristone REMS Program. Katzen Decl. Ex. 1, 2021 REMS 001568. That review encompassed

[1] The plaintiffs in another challenge to the same agency action have moved to complete or supplement the administrative record with the same citizen petition materials. *Chelius, et al. v. Becerra, et al.*, Civ. No. 1:17-00593-JAO-RT, ECF No. 198 (D. Haw. Nov. 30, 2023). Defendants have opposed that motion, *id.*, ECF No. 202, which will be argued on March 8, 2024, *id.*, ECF No. 201.

"multiple sources of information," including literature published between March 29, 2016 (the date of the last major REMS modification) and July 26, 2021. Katzen Decl. Ex. 1, 2021 REMS 001570.

On December 16, 2021, FDA concluded that the Mifepristone REMS Program should be retained but modified. Katzen Decl. Ex. 2, 2019 CP 000634. FDA accordingly directed mifepristone's sponsors to submit supplemental applications proposing the modifications that FDA had determined were necessary. Katzen Decl. Ex. 2, 2019 CP 000634; Katzen Decl. Ex. 3, 2021 REMS 001803-07; Katzen Decl. Ex. 4, 2021 REMS 001808-11. The sponsors did so in 2022, and FDA approved the applications on January 3, 2023 (the January 2023 REMS Modification). Katzen Decl. Ex. 5, 2023 SUPP 001119-28; Katzen Decl. Ex. 6, 2023 SUPP 001448-60; Katzen Decl. Ex. 7, 2023 SUPP 001461-65.

On October 22, 2022—after FDA's 2021 determination—the American College of Obstetricians and Gynecologists (ACOG) and 48 other organizations submitted a citizen petition requesting that FDA ask one of the sponsors of mifepristone to submit a supplemental application "to add miscarriage management as an indication to the mifepristone label and to modify the REMS so that it does not unduly burden its use for miscarriage management." ECF No. 61-1, at 2; *see id.* at 1. FDA denied that petition, explaining that the sponsors of mifepristone decide whether to seek approval for a new indication. ECF No. 1-20,

at 3. And "[b]ecause the management of miscarriage is not a currently approved indication for mifepristone," FDA explained, "it would be premature for FDA to consider the impact that the addition of this indication would have, if any, on the Mifepristone REMS Program so that it is not unduly burdensome for that use." *Id.* at 4.

ARGUMENT

Although Plaintiffs style their motion as one solely to "supplement" the administrative record, in substance they ask this Court to order FDA to either complete or supplement the administrative record. *See City of L.A. v. Dickson*, No. 19-71581, 2021 WL 2850586, at *1 n.2 (9th Cir. Jul. 8, 2021) (noting the different standards for completing and supplementing the administrative record). Neither course is appropriate here.

I. Plaintiffs Have Not Shown The Record Is Incomplete

In an Administrative Procedure Act case, review is ordinarily limited to the administrative record consisting of "all documents and materials directly or indirectly considered by the agency decision-makers" in reaching the particular decision under review. *Blue Mountains Biodiversity Project v. Jeffries*, 72 F.4th 991, 996 (9th Cir. 2023) (internal quotation marks omitted). Courts "presume that an agency properly designated the [a]dministrative [r]ecord" absent "clear evidence to the contrary." *Id.* at 997 (quotations omitted).

Plaintiffs have not provided *any* evidence, let alone clear evidence, that FDA considered the ACOG Citizen Petition documents or documents beyond those in the record from the "Turnaway Study," either directly or indirectly, in connection with the January 2023 REMS Modification. Plaintiffs argue that the ACOG Citizen Petition was "before" the agency in the sense of being in FDA's files prior to the January 2023 REMS Modification. Mot. 6-8. But the mere "fact that the agency possessed the documents prior to the [challenged] decision does not mean that they were 'before the agency' for purposes of judicial review under … 5 U.S.C. § 706." *Detroit Int'l Bridge Co. v. Gov't of Canada*, No. CV 10-476 (RMC), 2016 WL 10749142, at *2 (D.D.C. Apr. 25, 2016); *see Conservation Cong. v. U.S. Forest Serv.*, No. 2:13-cv-01922-TLN-CMK, 2016 WL 10637090, at *2 (E.D. Cal. Oct. 12, 2016) (holding that plaintiffs "cannot succeed simply by showing that the agencies were aware of [a document] or had [it] somewhere in their possession"). Rather, to be "before" the agency, the documents must have been directly or indirectly considered by the decisionmaker in taking *the challenged agency action*. *Blue Mountains Biodiversity Project*, 72 F.4th at 996. The documents covered by Plaintiffs' motion were not.

Nor should it be surprising that the ACOG Citizen Petition documents were not considered by the agency in connection with the January 2023 REMS Modification. As another court considering similar claims observed, the ACOG

Citizen Petition is "not directly relevant" to that agency action. *Whole Woman's Health All. v. FDA*, No. 3:23-CV-00019, 2023 WL 5401885, at *6 (W.D. Va. Aug. 21, 2023). Whereas the ACOG Citizen Petition pertained to an unapproved use of mifepristone for miscarriage management,[2] the January 2023 REMS Modification (and the preceding 2021 review) pertained to mifepristone's approved use for termination of early pregnancy. *See* Katzen Decl. Ex. 1, 2021 REMS 001571 (noting that FDA's review excluded data related to miscarriages because those data were "not applicable to the approved indication"). And ven if these documents were relevant, that alone would not be a basis to deem the produced record incomplete. *See Safari Club Int'l v. Jewell*, No. CV-16-00094-TUC-JGZ, 2016 WL 7785452, at *2 (D. Ariz. July 7, 2016).

Even further afield is Plaintiffs' contention that the mere *citation* of studies by other documents in the record or by the ACOG Citizen Petition means those studies should be part of the record. Mot. 7, 8. For example, Plaintiffs argue that the "Turnaway Study" is part of the record because it was cited in various record

[2] Although certain statements in the ACOG Citizen Petition were phrased broadly and not expressly limited to the use of mifepristone for miscarriage management, those statements were made in support of arguments that unambiguously concerned that unapproved use. *E.g.*, ECF No. 61-1, at 12.

documents. Mot. 8; ECF 135 at 2, ¶ 6.c. But they do not show that the produced record excludes any document that FDA directly or indirectly considered. To begin with, it is not even clear what "Turnaway Study" documents Plaintiffs are referring to. *See Audubon Soc'y of Portland v. Zinke*, Case No. 1:17-cv-00069-CL, 2017 WL 6376464, at *4 (D. Or. Dec. 12, 2017) (requiring moving party to "identify the materials alleged omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents … that are likely to exist") (internal quotation marks omitted). 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 publications. *See* Katzen Decl. Ex. 9, The Turnaway Study, https://perma.cc/J49Q-KFNW (reporting publication of "more than fifty scientific papers in the peer-reviewed journals using data from the Turnaway Study"). And several of those publications—the ones FDA considered—*are* included in the administrative record. *See, e.g.*, ECF No. 135, Ex. A, 2023 SUPP 000229 ("This study presents data from the Turnaway Study …").

That aside, the mere citation of documents in a record document does not, by itself, make the cited documents part of the administrative record. To be "indirectly considered," documents must be "so heavily relied on in [subordinates'] recommendation[s]" or in other materials directly considered by the decision maker "that the decision maker" can be said to have "constructively considered

them." *Safari Club*, 2016 WL 7785452, at *2 (quotations omitted). Consistent with that standard, courts "have rejected the argument that if a document considered by the agency decision-maker refers to other documents, those underlying documents must be included in the record." *Save the Colorado v. U.S. Dep't of the Interior*, 517 F. Supp. 3d 890, 898 (D. Ariz. 2021). To hold that being cited within a record document by itself establishes that the cited document is part of the record would "stretch the chain of indirect causation to its breaking point," *id.*, and create an infinite recursion: if a study cited in a record document becomes part of the record for that reason alone, so would all studies cited in that study, all studies cited in those studies, and so on.[3]

II. The Court Should Not Consider Extra-Record Material

Plaintiffs' alternative request to supplement the record with extra-record material also lacks merit. Courts "place a thumb on the scale against supplementation" of the record. *Blue Mountains Biodiversity Project*, 72 F.4th at

[3] Plaintiffs attempt to wave the problem away by suggesting that the produced record contains similarly cited material. Mot. 7. Not so. In connection with the January 2023 REMS Modification, FDA considered Dr. Chelius' and the States' letters and their references. But the record does not contain the equivalent of what Plaintiffs ask for: the references cited within the references to those letters.

998. If supplementation were routine, "it would be obvious that the federal courts would be proceeding, in effect, de novo rather than with the proper deference to agency processes, expertise, and decision-making." *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). Thus, to justify departing from the record-review rule, Plaintiffs must meet 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).

Plaintiffs claim (Mot. 8-10) the documents are "necessary to determine whether the agency has considered all relevant factors and has explained its decision." *Lands Council*, 395 F.3d at 1030 (internal quotation marks omitted). But this exception to the record-review rule is "narrowly construed and applied," *id.*, to prevent plaintiffs from "driv[ing] a truck through what is supposed to be a narrow exception to the record review rule," *Nw. Env't Advocs. v. U.S. Fish & Wildlife Serv.*, No. 3:18-CV-01420-AC, 2019 WL 6977406, at* 9 (D. Or. Dec. 20, 2019) (quotations omitted). It applies only when the agency "fail[ed] to consider a general subject matter that is demonstrably relevant to the outcome of the agency's decision, not when specific hypotheses and/or conclusions are omitted from consideration." *Ctr. for Biological Diversity v. Jewell*, No. CV-12-02296-PHX-DGC, 2014 WL 116408, at *2 (D. Ariz. Jan. 13, 2014) (quotations omitted); *see Organic Pastures Dairy Co. v. Sebelius*, No. 1:12-CV-02019-SAB, 2013 WL

4648548, at *5 (E.D. Cal. Aug. 29, 2013). It cannot be used "merely to bolster the record or supply background information." *Ctr. for Biological Diversity*, 2014 WL 116408, at *1.

Plaintiffs have not met their heavy burden to show the exception applies. The record spans more than 6,000 pages, including the detailed, 49-page REMS Modification Rationale Review, Katzen Decl. Ex. 1, and "contains sufficient information to explain how the [agency used the information before it] and why it reached its decision," *WildEarth Guardians v. U.S. Fish & Wildlife Serv.*, No. CV-13-00151-TUC-RCC, 2015 WL 13567455, at *3 (D. Ariz. Sept. 28, 2015) (quoting *Cook Inletkeeper v. EPA*, 400 F. App'x 239, 240–41 (9th Cir. 2010)).

Far from identifying any general subject matter that FDA failed to consider, Plaintiffs impermissibly seek to pad the record with additional evidence on specific issues. Moreover, the record shows that FDA considered those issues. Plaintiffs argue, for example, that the ACOG Citizen Petition documents show, based on data from Canada, that the Mifepristone REMS Program could be eliminated without an increase in complications or adverse events. Mot. 9-10. But the record reflects that FDA *did consider* evidence relating to Canada's experience. Katzen Decl. Ex. 1, 2021 REMS 001585–86. So, too, for the Turnaway Study, which, Plaintiffs say, shows that most women who seek abortions have "difficult financial situations" and that obtaining wanted abortions improves mental health. Mot. 10. The existing

record addresses these points. *See* Katzen Decl. Ex. 10, FDA 1255 (reporting that most abortion patients have "difficult financial situations"); Katzen Decl. Ex. 8, 2021 REMS 001198-226 (reporting low income for most abortion patients); ECF No. 135, Ex. A, 2023 SUPP 000229-238 (reporting positive mental health effects of wanted abortion).

Unable to explain why the record is inadequate, Plaintiffs argue that FDA "should have considered" the Turnaway Study and the studies cited in the ACOG Citizen Petition because they are allegedly relevant. Mot. 10. But "courts have expressly rejected the use of the 'relevant factors' test as grounds for the admission of extra-record evidence where the plaintiff argues that the new evidence *should* have been considered by the agency." *Safari Club Int'l*, 2016 WL 7785452, at *5 (emphasis in original). Plaintiffs can, of course, request a new agency action based on that evidence. *See* 21 C.F.R. § 10.45(f) ("An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a)."). But the Court should not consider that extra-record evidence in reviewing the agency action challenged here.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiff States' Motion to Supplement the Administrative Record.

February 2, 2024

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CERTIFICATE OF SERVICE

I hereby certify that, on February 2, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen
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