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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIVIL ACTION

Case No. 1-:17-cv-00493-JAO-RT

REPLY IN SUPPORT OF MOTION TO COMPLETE OR, IN THE ALTERNATIVE, SUPPLEMENT THE RECORD

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Resolution of this motion is straightforward. Defendants do not and cannot dispute FDA's dispositive admission that it "carefully considered" the citizen petition submitted by the American College of Obstetricians and Gynecologists ("ACOG") and 48 other organizations in October 2022 ("ACOG Petition" or "Petition").[1] Instead, Defendants argue that because the Petition principally sought relief from the REMS for miscarriage patients, the Petition was irrelevant to FDA's REMS Review. Neither fact nor law supports them. *First*, the *same* decisionmaker signed off on both the REMS update and the Petition denial on the *same* day,[2] belying Defendants' argument that the two actions were unrelated; Defendants have no response to this coordination other than asking this Court to ignore it. *See* Defs.' Opp'n Pls.' Mot. Complete or, in Alternative, Suppl. R. ("Opp'n Br.") 19 n.6, ECF No. 202. *Second*, the Petition addressed the precise questions at issue in FDA's REMS Review—whether a REMS for mifepristone is "necessary to ensure that the benefits of the drug outweigh the risks," 21 U.S.C. § 355-1(a)(1), and whether the Elements to Assure Safe Use ("ETASU") are "unduly burdensome on patient

[1] Letter from Patrizia A. Cavazzoni, M.D., Dir., Ctr. for Drug Eval. & Rsch., U.S. Food & Drug Admin., to Maureen G. Phipps, M.D., M.P.H., FACOG (Jan. 3, 2023) [hereinafter Denial Letter], Mot. Complete or, in Alternative, Suppl. R. ("Mot.") Ex. C, at 1, ECF No. 198-4.

[2] *Compare id.* at 4, *with* Ctr. for Drug Eval. & Res., U.S. Food & Drug Admin., REMS Review Memorandum 1 (Jan. 3, 2023) [hereinafter CDER REMS Review Memorandum], Am. & Suppl. Compl. Suppl. Ex. A, ECF No. 169-1.

access," *id.* § 355-1(f)(2)(C)—and expressly did so with respect to mifepristone's use for abortion. For instance, in a section called "Existing Data Demonstrate that a Removal of All REMS Requirements Will Not Harm Patient Safety," the ACOG Petition discussed data showing no negative safety impact "[a]fter Canada removed all restrictions on prescribing *mifepristone for abortion*."[3] *Third*, while Defendants claim that evidence focused on mifepristone for miscarriage was "outside the scope of FDA's review," Opp'n Br. 18–19, Defendants included in the administrative record multiple documents that relate exclusively to mifepristone's use for miscarriage care, *e.g.*, *id.* Exs. 3, 4—an admission that the agency, at minimum, "indirectly considered" such evidence in connection with the 2023 REMS update. *Thompson v. U.S. Dep't of Lab.,* 885 F.2d 551, 555 (9th Cir. 1989); *see also Ctr. for Food Safety v. EPA*, No. 23-CV-02714-SI, 2023 WL 8813528, at *3 (N.D. Cal. Dec. 19, 2023) ("[M]aterials provided to an agency during a decision-making process related to the subject matter of that decision logically fit within the category of 'indirectly considered.'"). The Petition, its references, and FDA's denial letter were plainly part of "the full administrative record that was before the [agency] at the time [it] made [its] decision," *Asarco, Inc. v. U.S. EPA*, 616 F.2d 1153, 1158–59 (9th Cir. 1980) (citation omitted).

[3] ACOG Pet., Mot. Ex. A, at 17, ECF No. 198-1 (emphasis added) (citations omitted).

Because these materials are necessary to complete the record, this Court need not reach Plaintiffs' alternative argument. But even if they were deemed "extra-record evidence," supplementing the record would be necessary to show "what matters the agency should have considered but did not." *Id.* at 1160. The district court in *Washington v. FDA* already preliminarily found that "FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth under 21 U.S.C. § 355-1(a)(1), (f)(1))." 668 F. Supp. 3d 1125, 1141 (E.D. Wash. 2023), *opinion clarified*, No. 1:23-CV-3026-TOR, 2023 WL 2941567 (E.D. Wash. Apr. 13, 2023). As Plaintiffs will show, this violation includes FDA's absolute silence regarding research discussed in the Petition that found *no negative safety impact* when Canada eliminated its REMS analogues—data that go to the core of the REMS statutory criteria.[4] In short, supplementing the record will help "show the existence of particular factors, approaches, or analyses that [FDA] did not utilize[,] . . . a purpose falling squarely with the first exception to the general rule barring extra-record evidence." *Conservation Council for Haw. v. Nat'l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1220 (D. Haw. 2015) (citation omitted).

I. ARGUMENT

A. The Petition Was Considered by the Agency and Is Interwoven with the 2023 REMS Update.

[4] ACOG Pet., Mot. Ex. A, at 17.

Plaintiffs have readily "overcome the presumption that the agency properly submitted a complete administrative record." *Xerces Soc'y for Invertebrate Conservation v. Shea*, No. 3:22-CV-00790-HZ, 2023 WL 4941221, at *5 (D. Or. July 17, 2023). Plaintiffs have "(1) identif[ied] reasonable, non-speculative grounds for [their] belief that the documents were considered by the agency and not included in the record, and (2) identif[ied] the materials allegedly omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents that are likely to exist." *Id.* (quoting *Audubon Soc'y of Portland v. Zinke*, No. 1:17-CV-00069-CL, 2017 WL 6376464, at *4 (D. Or. Dec. 12, 2017)); *accord Alegre v. United States*, No. 16-CV-2442-AJB-KSC, 2021 WL 4934982, at *4 (S.D. Cal. July 29, 2021) (citations omitted).

Far from "simply assert[ing] that the documents were relevant [and] were before or in front of the agency," Opp'n Br. 16 (quoting *Xerces*, 2023 WL 4941221, at *5), or offering "mere 'inferences,'" *id.* at 13–14 (quoting *Conservation Cong. v. U.S. Forest Serv.*, No. 2:13-CV-01922-TLN-CMK, 2016 WL 10637090, at *2, *4 (E.D. Cal. Oct. 12, 2016)), Plaintiffs put forward no less than a letter from the same FDA office that signed off on the updated REMS, on the same day it signed off on the updated REMS, admitting that FDA "carefully considered" the Petition.[5] *Cf.*

[5] Denial Letter, Mot. Ex. C, at 1.

California v. U.S. Dep't of Homeland Sec., 612 F. Supp. 3d 875, 887–88 (N.D. Cal. 2020) (finding a lack of clear evidence that the agency "indirectly considered" data where the data "not only was not cited in the Rule itself but was not cited in an article published the same day as the Rule."). Defendants nowhere acknowledged this admission, and could muster only a one-sentence footnote that the Court should ignore that the document was reviewed by the same personnel at the same time as the REMS was updated. Opp'n Br. 19 n.6. Instead, Defendants argued that a Petition seeking to eliminate the mifepristone REMS and FDA's review of the mifepristone REMS are apples and oranges. The facts do not bear this out.

As an initial matter, the ACOG Petition expressly addressed the lack of medical necessity for a REMS and why the ETASU are unduly burdensome in the context of abortion. *See* Mot. 6–8; Opp'n Br. 18 (admitting "certain statements in the petition were phrased broadly and not expressly limited to the use of mifepristone for miscarriage management"). Most notably, the Petition included a stand-alone section discussing data showing that "[a]fter Canada removed all restrictions on prescribing *mifepristone for abortion* . . . there was no increase in complications from mifepristone use."[6] There was no need for FDA to "comb through references appended to [the] petition" to find this research, Opp'n Br. 25 n.8: the ACOG

[6] ACOG Pet., Mot. Ex. A, at 17 (emphasis added) (citations omitted).

Petition discussed the Canadian study in detail. Having "carefully considered" the Petition,[7] FDA could not have missed these glaringly relevant data that go to the central question of its REMS review: whether a REMS is "necessary to ensure that the benefits of [mifepristone] outweigh the risks." 21 U.S.C. § 355-1(a)(1).[8]

That the Petition drew on data from the abortion context in articulating both the safety of mifepristone for miscarriage management and the burdens of the REMS is unsurprising[9]: whether used to end an ongoing pregnancy or to end a pregnancy

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[7] Denial Letter, Mot. Ex. C, at 1.

[8] Defendants' claim that the *Washington* court "did not find that the ACOG petition was relevant to the January 2023 REMS modification" is wrong, Opp'n Br. 22 n.7, and Defendants' contextless quote from another district court decision involving the REMS likewise misses the mark, *id.* at 22 (quoting *Whole Woman's Health All. v. FDA*, No. 3:23-CV-00019, 2023 WL 5401885, at *6 (W.D. Va. Aug. 21, 2023)). Both courts construed the ACOG Petition as "request[ing] FDA to *review and remove all mifepristone's REMS* to no avail," *id.*; *see also Washington*, 668 F. Supp. at 1139 (describing ACOG Petition as seeking to "eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily"—but not exclusively—"for miscarriage management"). Had those courts not viewed the Petition as inextricably linked to FDA's 2023 REMS update, they would not have relied on the denial of that Petition as prime evidence that another citizen petition asking FDA to reconsider its 2023 REMS update would be futile.

[9] There is no dispute that FDA's regulations on mifepristone apply equally when it is used to manage a miscarriage. Thus, as Defendant Secretary Becerra has explained, changes to those regulations "affect[] more than just access to abortion care. Some physicians use mifepristone for miscarriage management, which can be one of the most difficult times in a woman's life." U.S. Dep't of Health & Hum. Servs., *HHS Secretary Xavier Becerra Statement on Court Rulings on Mifepristone* (Apr. 7, 2023), https://www.hhs.gov/about/news/2023/04/07/hhs-secretary-xavier-becerra-statement-court-rulings-mifepristone.html [https://perma.cc/S8U8-KJFJ].

that is already doomed, 200 mg mifepristone is taken in a combined regimen with misoprostol, and in both cases the treatment regimen is extremely safe.[10] Moreover, both miscarriage and abortion patients are disproportionately likely to be poor, compounding the burdens imposed by the REMS.[11] Mifepristone is extremely safe, and the REMS imposes burdens, whether the drug is used in either the miscarriage or abortion context.

Moreover, FDA's construction of the record belies Defendants' arguments that "[m]iscarriage management . . . was outside the scope of FDA's review." Opp'n Br. 18–19. The record includes multiple documents relevant only to the use of

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[10] *Compare* Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161, 2169 (2018), Opp'n Br. Ex. 3, ECF No. 202-4 ("Studies of the use of mifepristone for induced abortion or for the treatment of early pregnancy loss have not shown a risk profile that supports . . . regulatory limitations on prescription."), *and* Am. Coll. Obstetricians & Gynecologists, *ACOG Practice Bulletin No. 200: Early Pregnancy Loss* (Nov. 2018), Opp'n Br. Ex. 2, ECF No. 202-3, *with* Admin. R. ("AR") at 2023 SUPP 001471, 001490 (Mifeprex, Mifepristone 2023 Labeling and Medication Guide).

[11] *See* ACOG Pet., Mot. Ex. A, at 3 ("Miscarriage . . . is more common among groups negatively impacted by societal dynamics of power and oppression, such as pregnant people who are Black, poor, or exposed to environmental pollutants. These risk factors have compounding effects when it comes to health equity, as people of color are both more likely to be exposed to pollution and more likely to live in poverty." (citations omitted)); Defs.' Resp. Opp'n Pl. States' Mot. Suppl. Admin. R. at 9–10, *Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. Feb. 2, 2024), ECF No. 139 (noting that studies in Administrative Record reflect that most abortion patients have "low income[s]" and "difficult financial situations").

mifepristone for miscarriage, including an ACOG practice bulletin on "early pregnancy loss," Opp'n Br. Ex. 2, and a study showing that mifepristone increases the efficacy of miscarriage treatment, Opp'n Br. Ex. 4.[12] Under the artificial parameters Defendants now attempt to draw, those miscarriage-focused materials would have been omitted from the record. Instead, FDA included them as part of the "whole record" under 5 U.S.C. § 706, an admission that the agency at least indirectly considered them.

In *Center for Food Safety v. EPA*, decided in December 2023, a district court for the Northern District of California rejected strikingly similar arguments raised by a different federal agency. The plaintiffs in *Center for Food Safety* challenged a citizen petition denial by the U.S. Environmental Protection Agency ("EPA") and sought to compel EPA "to complete or in the alternative supplement the administrative record" with related documents obtained through a Freedom of Information Act ("FOIA") request. EPA maintained that the FOIA production was

[12] *See also* Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161 (2018), AR at 2021 REMS 000568–77, 2019 CP 00402–411; Am. Coll. Obstetricians & Gynecologists, *ACOG Practice Bulletin No. 150: Early Pregnancy Loss* (May 2015), AR at 2023 SUPP 000038–46; Am. Coll. Obstetricians & Gynecologists, *ACOG Practice Bulletin No. 200: Early Pregnancy Loss* (Nov. 2018), AR at 2021 REMS 000578–88; Carolyn L. Westhoff, *A Better Medical Regimen for the Management of Miscarriage*, 378 New Eng. J. Med. 2232 (2018), AR at 2023 SUPP 00069–70.

"much broader" than and "outside the scope of the [p]etition," and argued that its "possession of certain records, . . . [wa]s not sufficient to show that the same records were considered by the agency." 2023 WL 8813528, at *4. Nevertheless, because "[t]he FOIA documents all concern the subject matter of the [p]etition, some of the documents reference the [petition], and the documents are all from the time period during which the [p]etition was pending before the EPA," the court granted plaintiffs' motion to complete the record (and thus found it unnecessary to reach the question of supplementation). *Id.* As the court explained, "materials provided to an agency during a decision-making process related to the subject matter of that decision logically fit within the category of 'indirectly considered,' and the Court has not found case law to the contrary." *Id.* at *3.[13]

[13] Defendants narrowly define the "indirectly considered" standard to encompass only materials "constructively considered" by the agency decisionmakers even where the materials "may not have literally passed before the[ir] eyes." Opp'n Br. 12–13 (quoting *Safari Club Int'l v. Jewell*, No. CV-16-00094-TUC-JGZ, 2016 WL 7785452, at *2 (D. Ariz. July 7, 2016)). But Defendants cite no case holding that the Ninth Circuit's broad "indirectly considered" standard is limited only to that fact pattern and does not also apply, consistent with common sense, where the relevant agency decisionmakers have considered materials interwoven with the challenged agency action. *See Ctr. for Food Safety*, 2023 WL 8813528, at *3; *see also Oceana, Inc. v. Raimondo*, No. 21-CV-05407-VKD, 2022 WL 17178301, at *6 (N.D. Cal. Nov. 23, 2022) ("Even if, as [the agency] argues, the rebuilding plan is an independent agency action, the plan still directly implicates the harvest control rules. Because the harvest control rules are an integral part of the rebuilding plan, documents . . . presented to [the agency] discussing and analyzing the merits of the harvest control rules and their underlying parameters were necessarily indirectly considered by [the agency].").

Here, too, the Petition concerns the same subject matter as FDA's REMS reviews: whether a REMS is necessary to ensure that the benefits of mifepristone outweigh its risks in the abortion context (and by extension the miscarriage context) and whether the ETASU are unduly burdensome on patient access to mifepristone in the abortion context (and by extension the miscarriage context).[14] The Petition "references" FDA's REMS reviews.[15] And it was not only pending while FDA conducted its final REMS Review, but "carefully considered" by the agency's Center for Drug Evaluation and Research ("CDER") and denied on January 3, 2023, the very same day that CDER completed its REMS review and approved the updated regulations.[16] Under Ninth Circuit precedent, "'[t]he whole record' includes everything that was before the agency pertaining to the merits of its decision." *Portland Audubon Soc'y*, 984 F.2d at 1548 (citing *Thompson*, 885 F.2d at 555–56). That plainly includes the Petition, its references,[17] and FDA's denial letter.

[14] ACOG Pet., Mot. Ex. A, at 11–17.

[15] *Id.* at 12 (discussing 2016 REMS Review), 15 (discussing "new pharmacy certification requirement" that was "yet to be finalized").

[16] Denial Letter, Mot. Ex. C, at 1, 4; CDER REMS Review Memorandum, Am. & Suppl. Compl. Suppl. Ex. A, at 1.

[17] Defendants did not and cannot dispute that throughout the record, FDA not only included citizen petitions and letters but also the materials referenced in those

B. Even If the Petition Were Extra-Record, Supplementation Would Be Proper to Show FDA's Failure to Address Major Categories of Evidence Relevant to the Statutory REMS Factors.

Defendants offer conclusory reassurances that the record "contains sufficient information to explain" the agency's decisionmaking process, and that FDA "thoroughly considered" the relevant statutory factors before maintaining the mifepristone REMS and two of its Elements to Assure Safe Use ("ETASU") and adding a third ETASU. Opp'n Br. 20, 22–23. FDA purports to prove this by listing broad categories of sources from which it drew information; citing data that it considered with respect to a former REMS requirement (in-person dispensing) that is no longer part of this case; and quoting three sentences in which FDA used the word "burden." *Id.* at 20–24. But "the [C]ourt cannot adequately discharge its duty to engage in a 'substantial inquiry'" under the Administrative Procedure Act ("APA") "if it is required to take the agency's word that it considered all relevant matters." *Asarco, Inc.*, 616 F.2d at 1160; *see also, e.g.*, *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, No. 3:01-CV-00640-SI, 2015 WL 423090, at *4 (D. Or. Feb. 2, 2015) (rejecting as "not . . . persuasive the Objecting Defendants' argument that there already is a voluminous record that has addressed all of the relevant factors and, thus, extra-record material is unnecessary.").

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petitions and letters. *See generally* AR Certification, Mot. Ex. E, ECF No. 198-6. Thus, if the Petition is properly a part of the whole record, so too are its references.

For the reasons detailed in *supra* Part (A), this Court need not reach the question whether the Petition and related materials are "necessary to determine 'whether the agency has considered all relevant factors and has explained its decision.'" *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). But even if these documents were not part of the whole record (which they are), they should be admitted as extra-record evidence to show "what matters the agency should have considered but did not." *Asarco, Inc.*, 616 F.2d at 1160; *see also Trout Unlimited v. Lohn*, No. C05-1128C, 2006 WL 1207901, at *3 (W.D. Wash. May 4, 2006) ("[D]ocuments 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." (emphasis in original)); *High Sierra Hikers Ass'n v. U.S. Dep't of the Interior*, No. C-09-4621 JCS, 2011 WL 2531138, at *8 (N.D. Cal. June 24, 2011) (agreeing that supplementation is proper for extra-record documents that "were not considered" but "*should have been* considered" (citing *Trout,* 2006 WL 1207901, at *3) (emphasis in original));[18] *Audubon Soc'y of*

[18] Defendants apparently ask this Court to disregard both *High Sierra* and *Trout* because *Trout* failed to invoke the magic word "exception." *See* Opp'n Br. 25 ("*Trout Unlimited* failed to follow *Lands Council*'s holding that supplementation is proper only when a document meets one of the narrow exceptions to the record-review rule."). But there is no meaningful daylight between *Trout* and *Lands Council*. Citing *Lands Council*, *Trout* cautioned against inappropriate use of "extrinsic data," and consistent with *Lands Council*, condoned extra-record evidence where necessary to assess whether "the agency . . . entirely failed to consider an

Portland v. U.S. Army Corps of Eng'rs, No. 3:15-CV-0665-SI, 2015 WL 13649299, at **2–4 (D. Or. May 5, 2015) (ordering government to supplement record with all "communications, email, notes, studies, and analyses prepared . . . by outside personnel or entities" relevant to the effectiveness of government's plan to increase salmon by reducing bird population, because that information will help the Court "determine whether consideration of the effectiveness of the cormorant management plan on salmon and steelhead survival was a relevant factor the agencies should have considered" (citation omitted)); *Alaska v. U.S. Dep't of the Interior*, No. 3:22-CV-00078-SLG, 2023 WL 2424270, at *7 (D. Alaska Mar. 9, 2023) ("In general, courts are inclined to supplement administrative records when the proffered documents are relevant and help them evaluate whether the agency considered all relevant factors."); *Sequoia Forestkeeper v. Benson*, No. 1:14-CV-00341 LJO, 2015 WL 1012364, at *3 (E.D. Cal. Mar. 5, 2015) (supplementing record under "relevant factors" exception and rejecting as "circular" agency's argument that its reports proved that the agency considered all relevant environmental impacts, because each report simply "assumes that because a conclusion was reached it must have been based on a valid analysis").

As Plaintiffs detailed in their Motion (at 13–15), their APA claim centers on

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important aspect of the problem." 2006 WL 1207901, at **1, 3 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983)).

FDA's failure to address key categories of evidence demonstrating that a REMS is unnecessary to ensure that mifepristone's benefits outweigh its "exceedingly rare" risks, Am. & Suppl. Compl. ¶¶ 123, 133, ECF 169 (quoting FDA's 2016 Medical Review); that the mifepristone ETASU are not "commensurate with" those risks, 21 U.S.C. § 355-1(f)(2)(A); and that the ETASU are "unduly burdensome on patient access to the drug, considering in particular . . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)," *id.* § 355-1(f)(2)(C). The Petition that FDA "carefully considered" prominently discussed data showing that when Canada eliminated its prescriber certification and patient consent form requirements for mifepristone and allowed "normal prescribing," Mot. 14 & n.29, there was *no increase in complications*.[19] Yet FDA nowhere addressed these data in determining that a REMS including prescriber certification, patient consent form, and pharmacy certification ETASU is "necessary," "commensurate," and "not . . . unduly burdensome" on patient access. 21 U.S.C. § 355-1(a)(1); *id.* § 355-1 (f)(2)(A), (C). There can be no doubt that this "general subject matter . . . is demonstrably relevant to the outcome of the agency's decision" and not mere "background information." Opp'n Br. 21–22 (quoting *Ctr. for Biological Diversity v. Jewell*, No. CV-12-02296-PHXDGC, 2014 WL 116408,

[19] ACOG Pet., Mot. Ex. A, at 17.

at **1–2 (D. Ariz. Jan. 13, 2014)). And FDA's suggestion that it already covered the waterfront on Canadian data by considering a single Canadian study on the wholly unrelated topic of telemedicine versus in-clinic dispensing only undermines their cause. *See id.* at 23.

Because the Petition and its references "show the existence of particular factors, approaches, or analyses that [the agency] did not utilize," *Conservation Council for Haw.*, 97 F. Supp. 3d at 1220, supplementation is proper.[20]

II. CONCLUSION

For the reasons set forth above and in Plaintiffs' motion, this Court should compel FDA to complete the record by adding the ACOG Petition, all references not already reflected in the record, and FDA's denial letter. At minimum, those materials readily meet the standard for supplementation of the record.

[20] Plaintiffs note that Defendants' "general subject matter" test comes from out-of-district decisions tracing back to a 2010 decision from the Eastern District of California. *E.g.*, *Ctr. for Biological Diversity*, 2014 WL 116408, at *2 (quoting *Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1234 (E.D. Cal. 2013)); *Organic Pastures Dairy Co. v. Sebelius*, No. 1:12-CV-02019-SAB, 2013 WL 4648548, at *5 (E.D. Cal. Aug. 29, 2013) (quoting same); *Pinnacle*, 923 F. Supp. 2d at 1234 (quoting *In re Delta Smelt Consol. Cases*, No. 1:09-CV-1053 OWW DLB, 2010 WL 2520946, at *5 (E.D. Cal. June 21, 2010)). That "general subject matter" framing was nowhere mentioned in this district's 2015 decision ordering supplementation of the record under the first *Lands Council* exception, *Conservation Council for Haw.*, 97 F. Supp. 3d at 1220. Regardless, Plaintiffs easily satisfy the standard as Defendants have framed it.

Respectfully submitted,

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